EXHIBIT A

Docket No. 022956-0214
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Shelby L. Cook et al.	Confirmation No. 9377
Application No. 10/615,625	Art Unit: 3731
Filed: June 27, 2003	Examiner: Tuan Van Nguyen
For: BIOABSORBABLE SUTURE ANCHOR SYSTEM FOR USE IN SMALL JOINTS	

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: January 22, 2008 Signature: _____
(Ronald E. Cahill)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of Jose E. Lizardi Pursuant to Rule 132

Dear Sir:

I, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, hereby declare as follows:

1. I am a joint inventor of the subject matter described and claimed in the above-identified patent application (the Application) and I make this Declaration in support of an Amendment and Response to Non-Final Office Action.

2. I am presently a Staff Engineer in the Research and Development area at DePuy Mitek, Inc., where I have been employed for more than 11 years. I have been working with and developing bone anchors during the entirety of my tenure at DePuy Mitek. Prior to working at

DePuy Mitek, I was employed for approximately four years as an engineer at Smith & Nephew. I worked with and developed bone anchors during the entirety of my tenure at Smith & Nephew as well. My background includes a Bachelor of Science degree in Applied Mathematics and Engineering from the University of South Florida, which I received in 1986.

3. I have read the Application and I fully understand the materials disclosed and claimed therein.

4. The Application is directed to suture anchors, systems, and a method for anchoring tissue to bone that relies on a particular geometry to create directed toggling that is particularly useful in small bones.

5. I have also read U.S. Patent No. 6,270,518 to Pedlick et al. ("Pedlick") and U.S. Patent No. 6,773,436 to Donnelly et al. ("Donnelly"), and I fully understand the inventions disclosed therein. I also understand that the claims of the above-referenced patent application stand rejected as being anticipated by Pedlick, anticipated by Donnelly, and obvious over a combination of Pedlick and Donnelly.

6. The claimed suture anchors are all configured particularly to be toggled inside small bones such as those found in the smaller joints in the body in order to repair soft tissue in those areas. The anchors can be useful in a variety of different procedures, including in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand, and for attaching soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. They are particularly useful in these types of procedures because of their small size and their geometry. More specifically with regard to the geometry, the suture channel 32 is oriented substantially transverse at right angles to the longitudinal axis of symmetry L of the body 12 and is laterally offset with respect to the longitudinal axis of symmetry L of the body 12 when observed from a centerline of the suture channel 32. The suture channel 32 is laterally offset on the opposite side of the longitudinal axis of symmetry L of the body 32 when compared to the flared portion 24 of the suture anchor 10. This geometry allows the suture anchor 10 to be toggled by pulling on a

strand of suture situated in the suture channel 32 so that the flared portion 24 toggles into the bone, which as illustrated in the embodiment of FIGS. 2A and 2B from the application and reproduced below, would cause the flared portion 24 to toggle in the generally counter-clockwise direction (with respect to FIG. 2A).

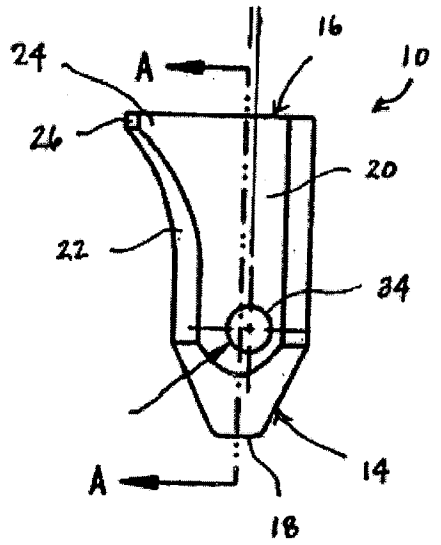
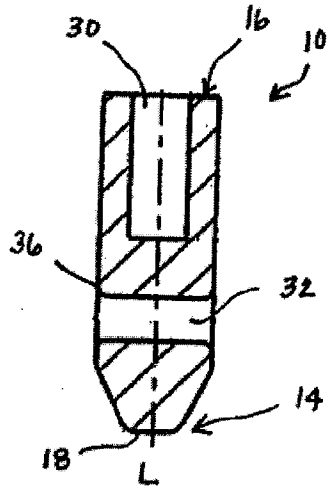


FIG. 2A



SECTION A—A

FIG. 2B

7. Prior to the invention, suture anchors for use in small spaces like those referred to in Paragraph 6, primarily relied upon screws, threads, and barbs to attach tissue to bone. *See at least* U.S. Patent No. 5,522,845 to Wenstrom, Jr., U.S. Patent No. 5,611,814 to Lorenc, U.S. Patent No. 5,950,633 to Lynch et al., *Treatment of Thumb Ulnar Collateral Ligament Ruptures with the Mitek Bone Anchor* by Scott H. Kozin, *Endoscopic Brow Lifts* by Keith F. Brewer, *Biofix® Ligament Tack: Biodegradable Ligament Injury Fixation Tacks Surgical Techniques I* by Pentti Rokkanen et al., *Surgical Technique: Scapholunate Surgical Technique Using the Mitek 2.0 mm Tacit™ Threaded Anchor* by Walter H. Short, *Surgical Technique: Endoscopic Browlift with Rigid Fixation Using the Mitek 2.0 mm Tacit™ Threaded Anchor* by Eduardo Barroso et al., *Product Brochure for the Mitek® 1.3 mm Micro Anchor*, and *Product Brochure for the Mitek®*

2.0 mm Tacit™ Threaded Anchor. While some forms of toggling suture anchors were known for use in large bones prior to the invention, to the best of my knowledge no suture anchors existed that were capable of toggling in such small spaces as the suture anchor of the Application can. This is because the structures in which the suture anchors were used were too small to handle the types of toggling suture anchors that were known. Prior to the Application, it was not known how to design a suture anchor that was small enough to work in those structures and also toggle. Accordingly, those of ordinary skill in the art instead developed non-toggling anchors for use with such small bones, such as anchors with threads and screws.

8. During the same year that the present application was filed, embodiments of the suture anchor as claimed were marketed and sold commercially as both the MINILOK™ and MICROFIX™ suture anchors. It is my understanding that marketing and sales for the suture anchors were performed in the normal course of business. It is also my understanding that the suture anchors have sold well and are still offered for sale today, in particular for uses with surgeries involving the attachment of tissue to bones in the hand and face. Doctors and others purchasing the suture anchors prefer the toggling suture anchors for such use as opposed to the thread or screw suture anchors because the toggling causes less damage to the bone and causes a more secure and exact fit between the tissue and the bone the tissue is being attached to. Ever since the suture anchors were offered for sale in 2003, they have been a success. The commercial success of the suture anchors continue even today as the advantages provided by the first toggling suture anchors for use in small areas such as bones in the hand and face are still realized and appreciated as an industry standard.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true.

Date: 1/18/2008

Jose E. Lizardi
Staff Engineer, Research and Development
DePuy Mitek, Inc.

1698745.1

US005522845A

United States Patent [19]

Wenstrom, Jr.

[11] Patent Number: 5,522,845

[45] Date of Patent: Jun. 4, 1996

[54] **BONE ANCHOR AND BONE ANCHOR INSTALLATION**

[75] Inventor: **Richard F. Wenstrom, Jr.**, Attleboro, Mass.

[73] Assignee: **Mitek Surgical Products, Inc.**, Westwood, Mass.

[21] Appl. No.: **312,894**

[22] Filed: **Sep. 27, 1994**

[51] **Int. Cl.**[6] **A61B 17/04**

[52] **U.S. Cl.** **606/232**; 606/72; 606/78

[58] **Field of Search** 606/232, 72–77, 606/104, 78

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,207,679	5/1993	Li	606/232
5,217,486	6/1993	Rice et al.	606/232
5,358,511	10/1994	Gatturna et al.	606/232

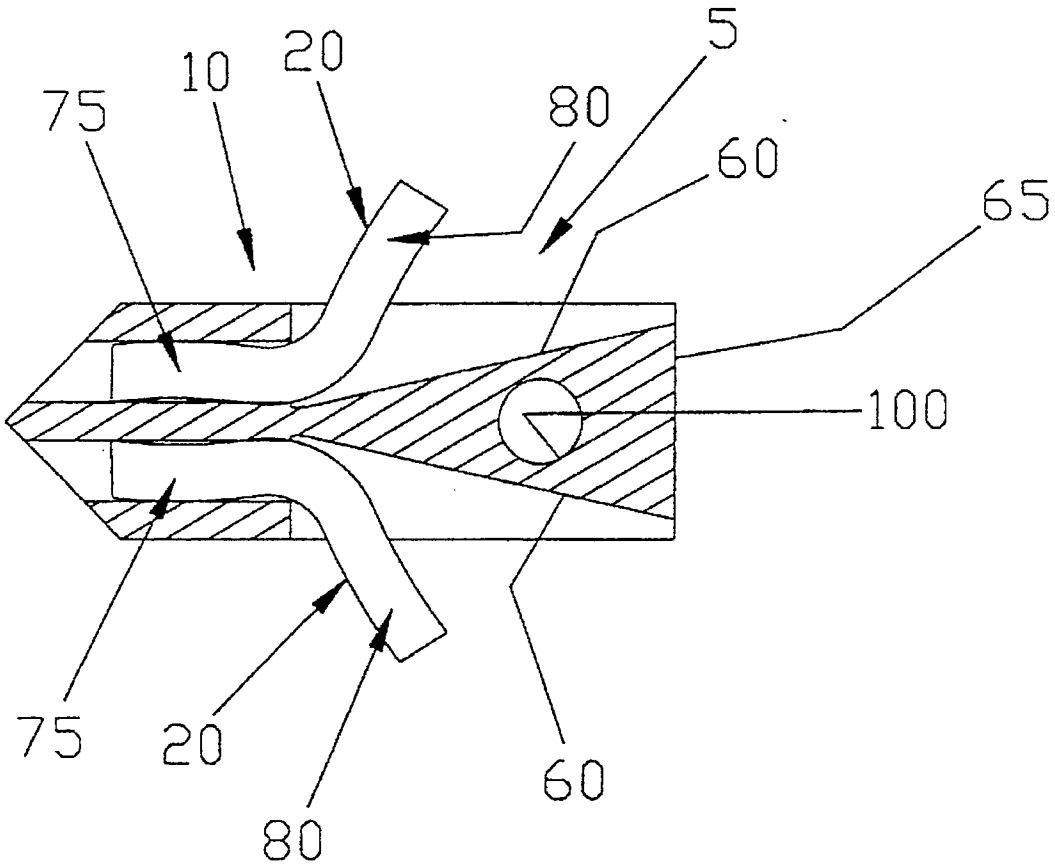
Primary Examiner—Gary Jackson

Attorney, Agent, or Firm—Pandiscio & Pandiscio

[57] **ABSTRACT**

A bone anchor and a bone anchor installation tool for deploying the bone anchor in bone.

11 Claims, 15 Drawing Sheets



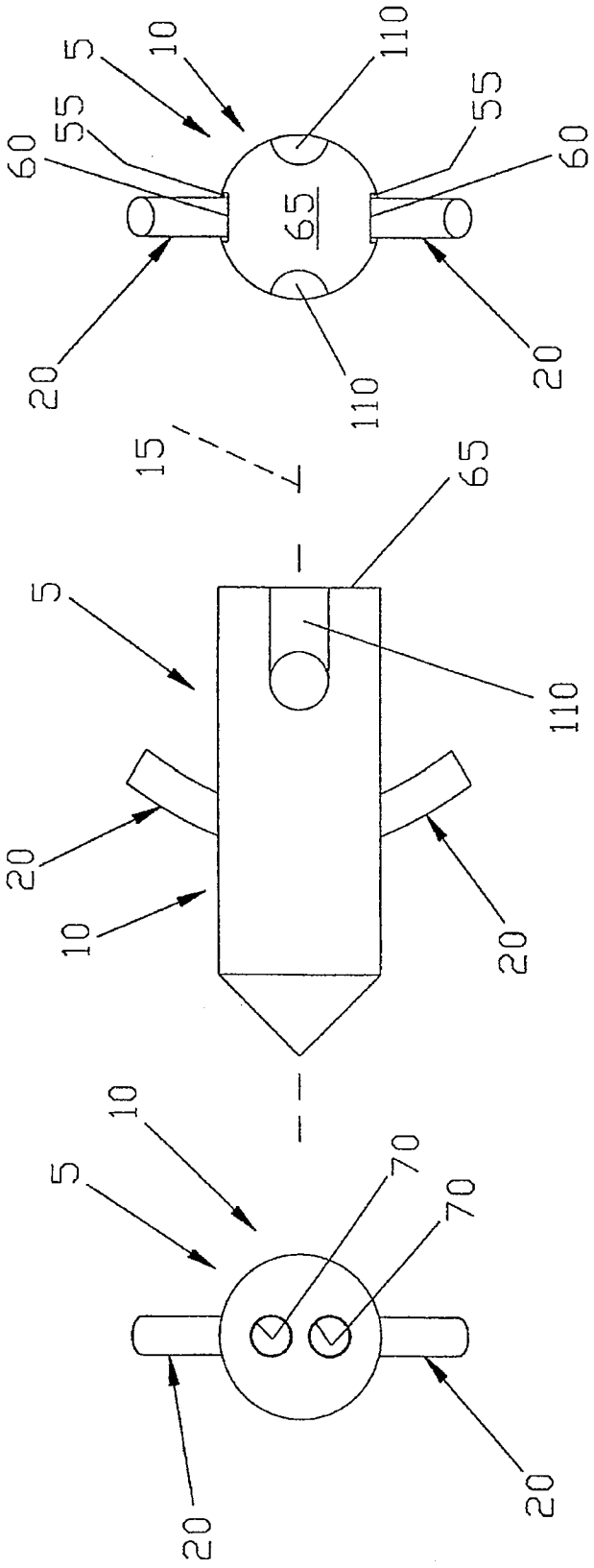


FIG. 3

FIG. 1

FIG. 2

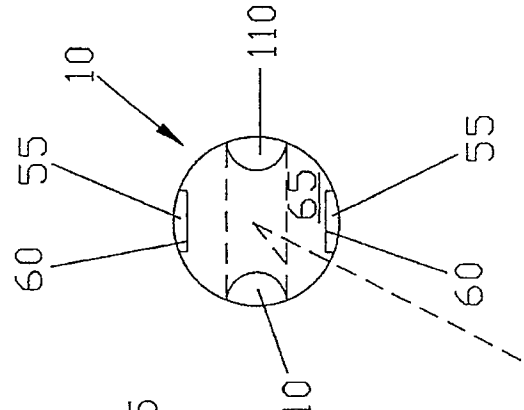
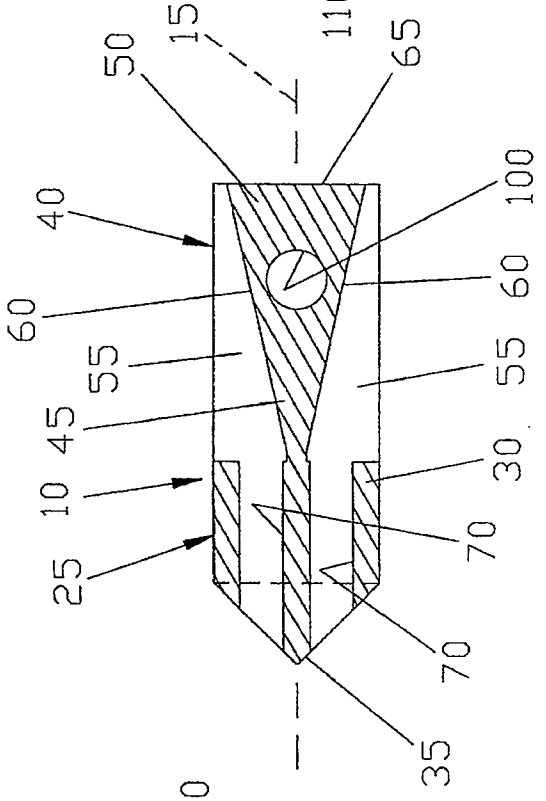


FIG. 6



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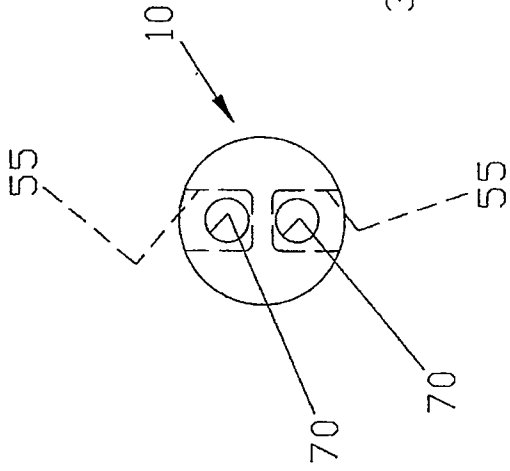


FIG. 5

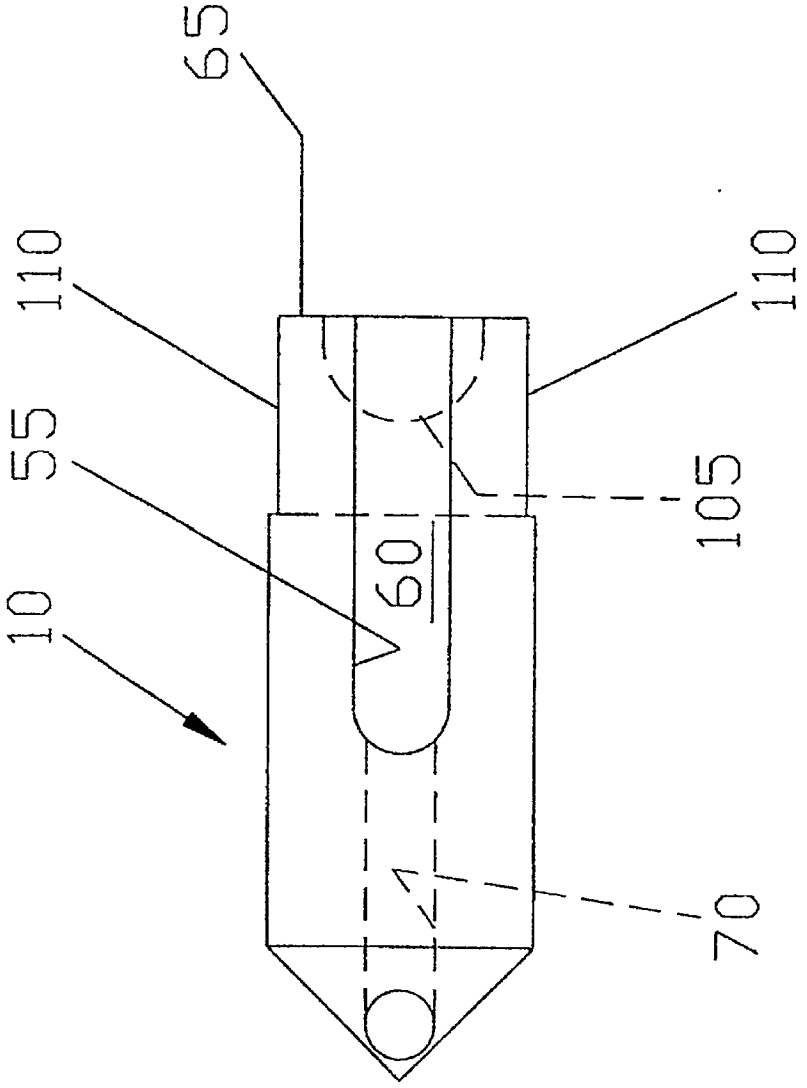


FIG. 7

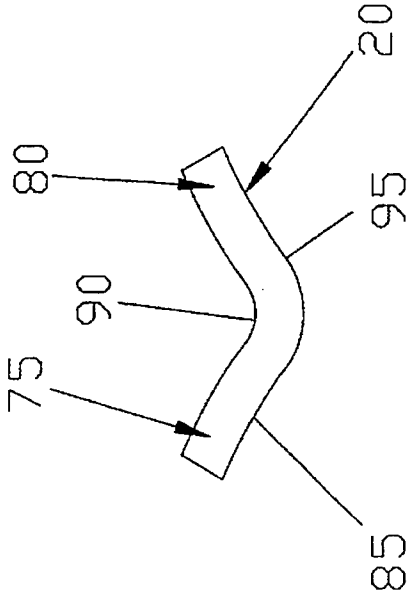
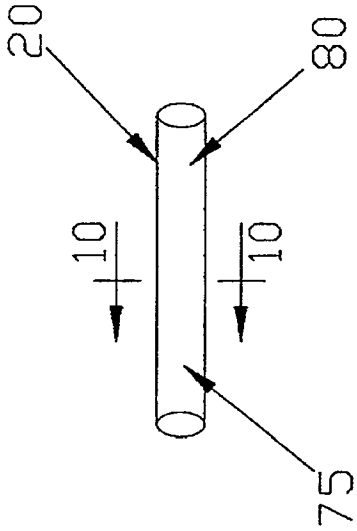


FIG. 8



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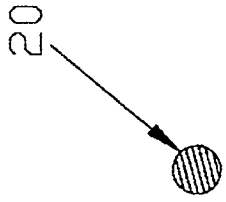
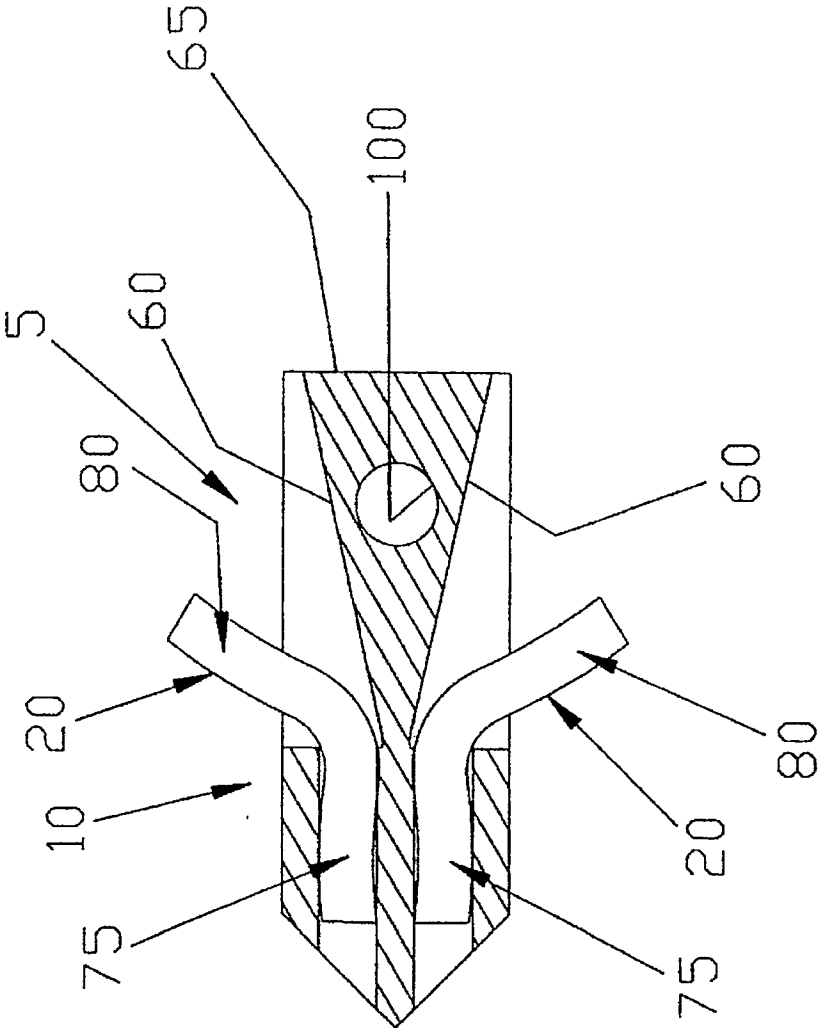


FIG. 10



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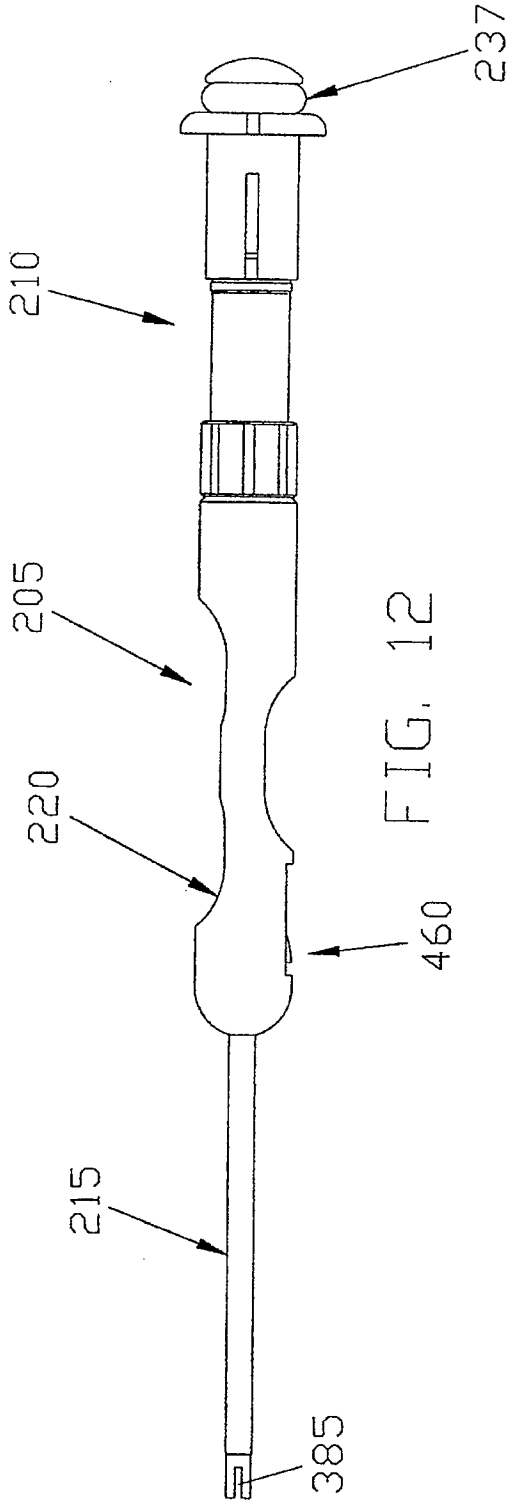

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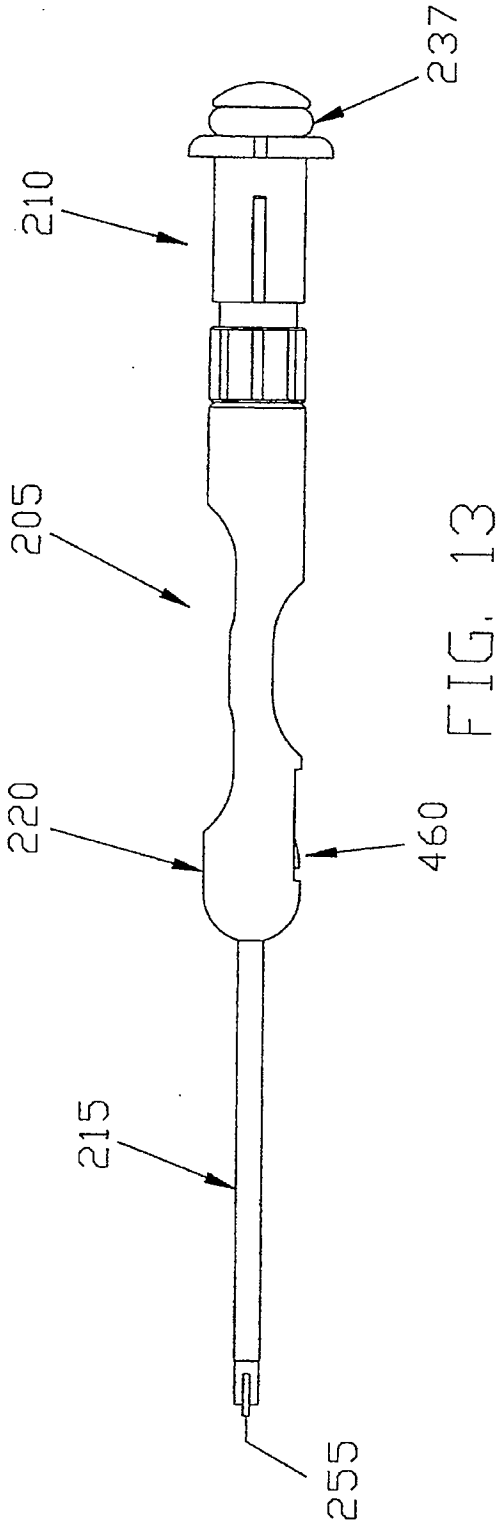

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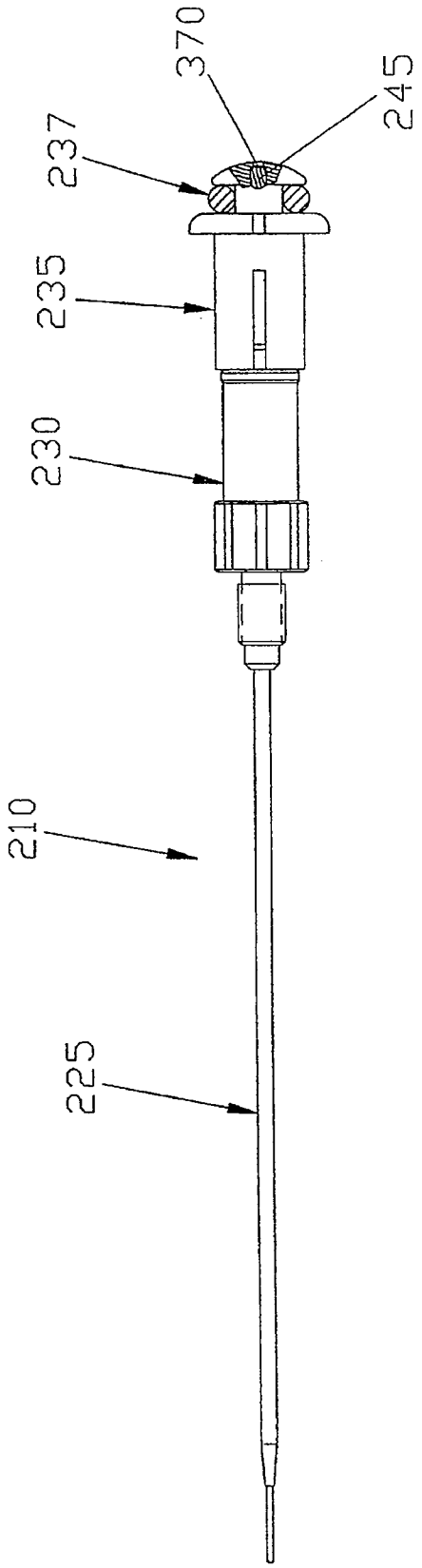

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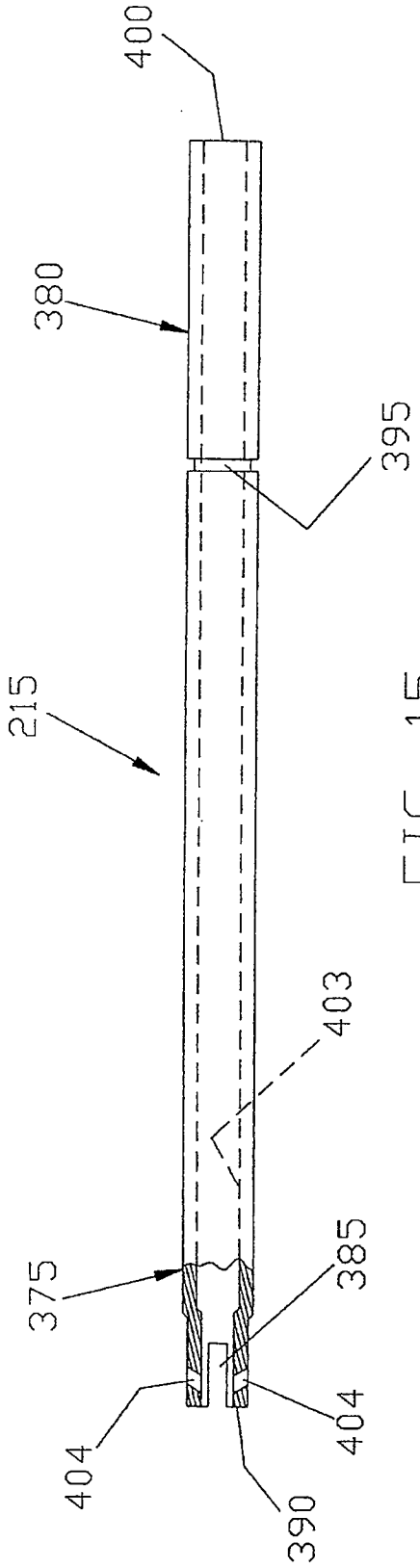
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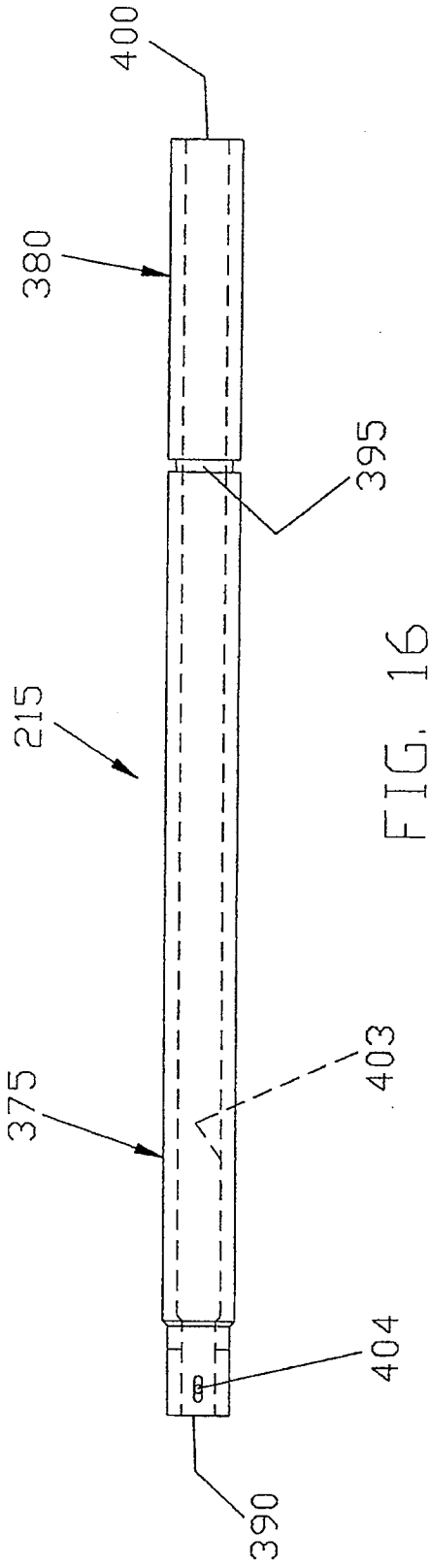
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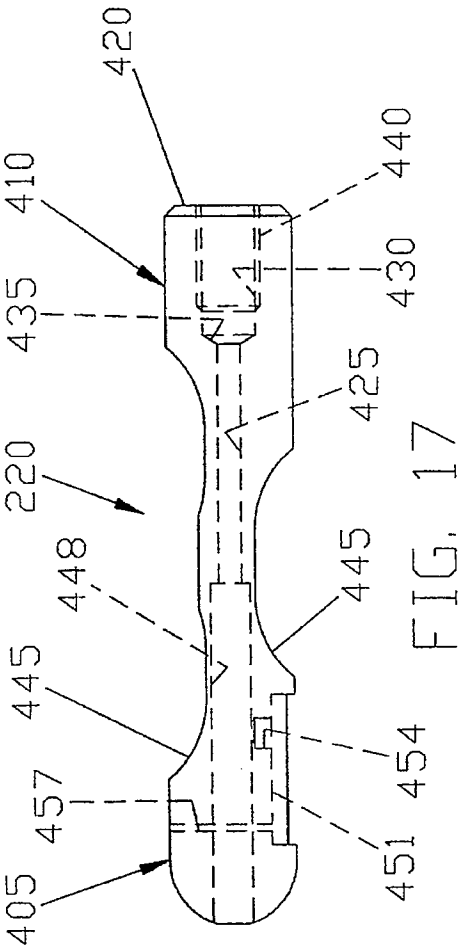

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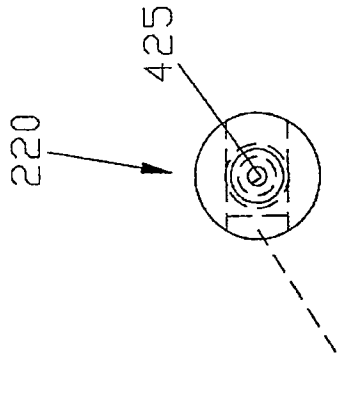

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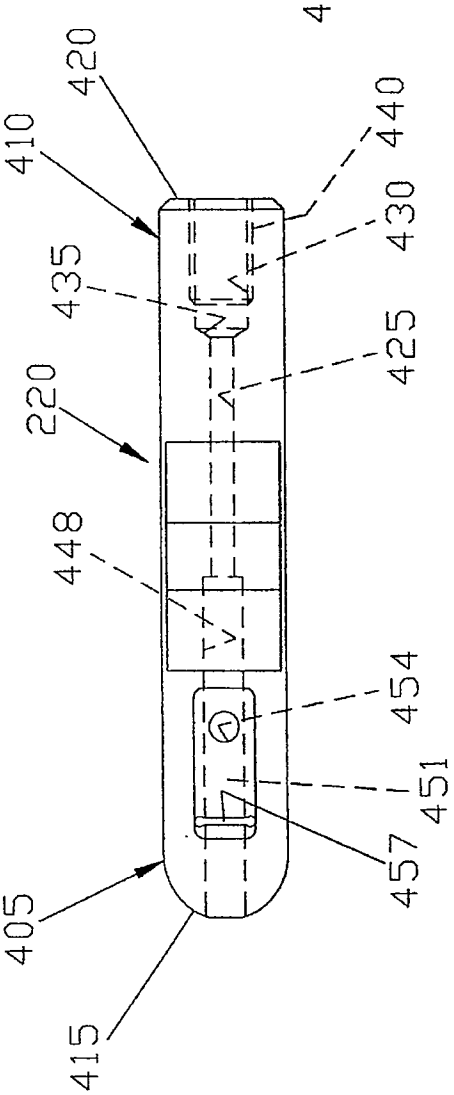

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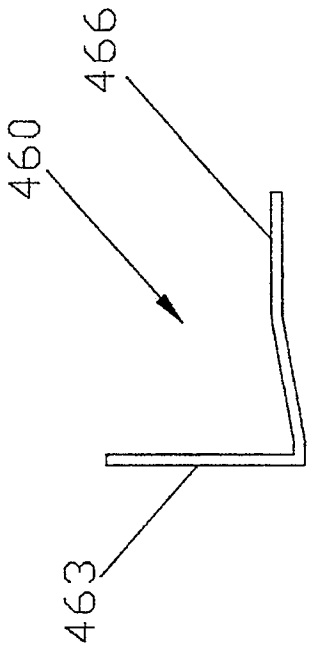

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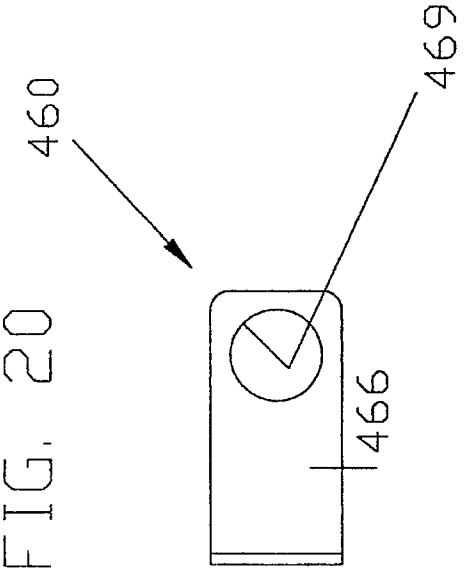
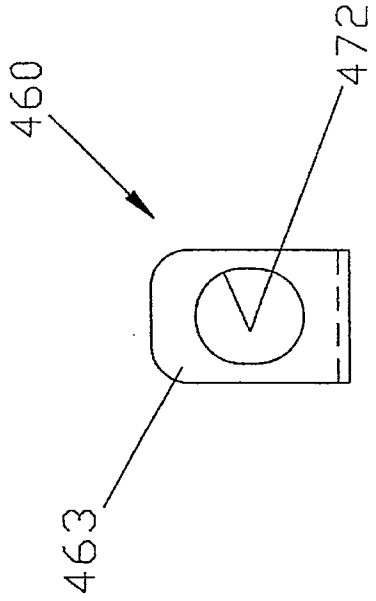


FIG. 22



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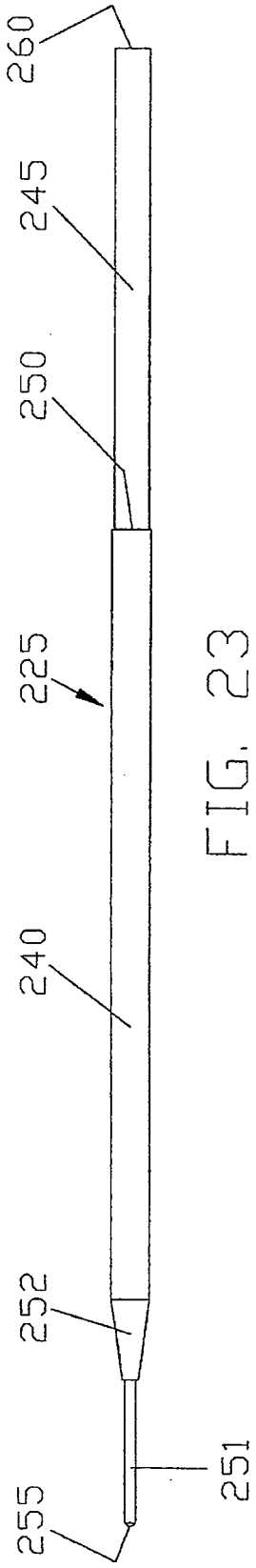

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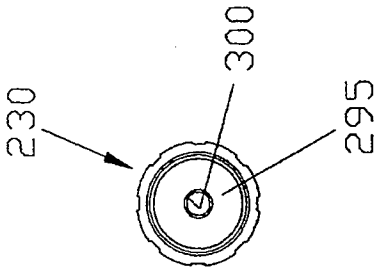

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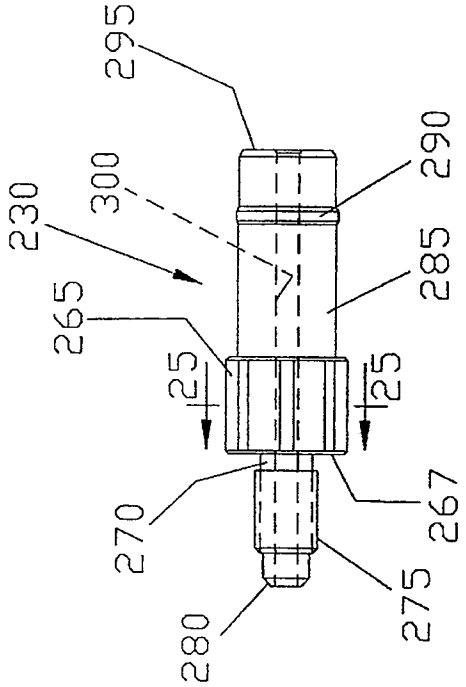

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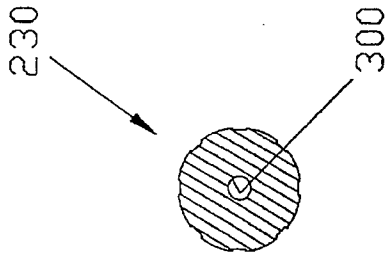

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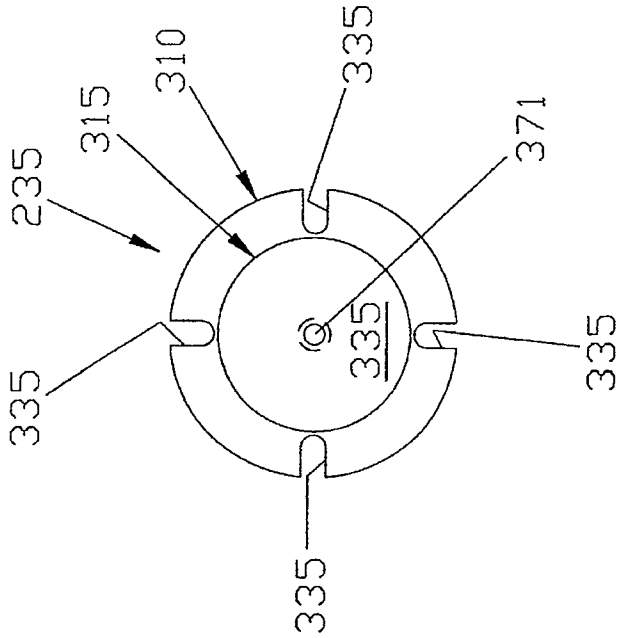
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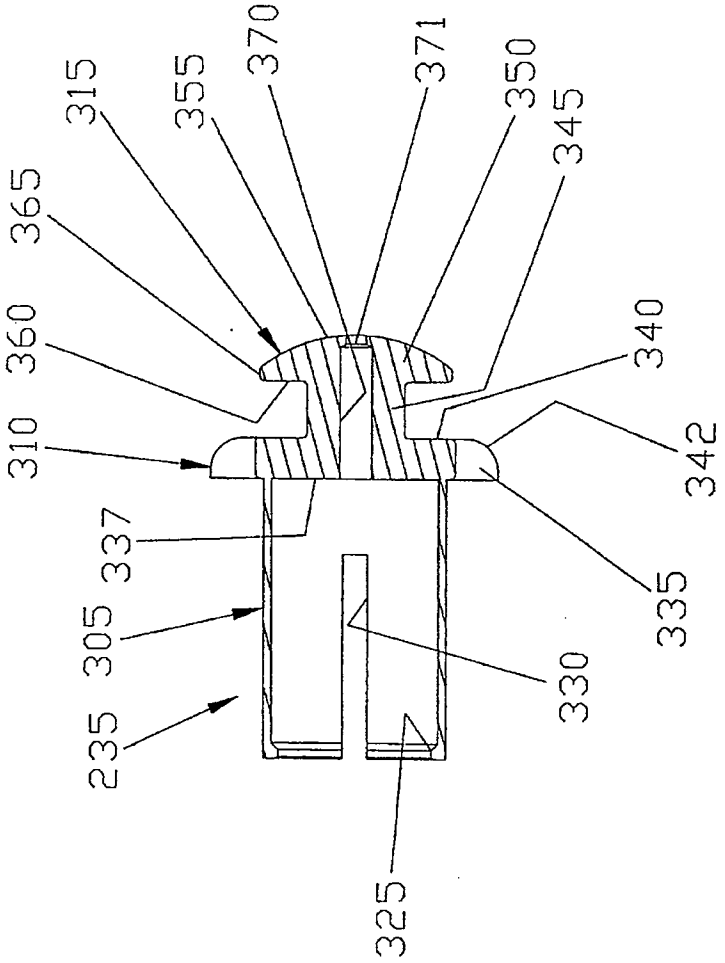
FIG. 28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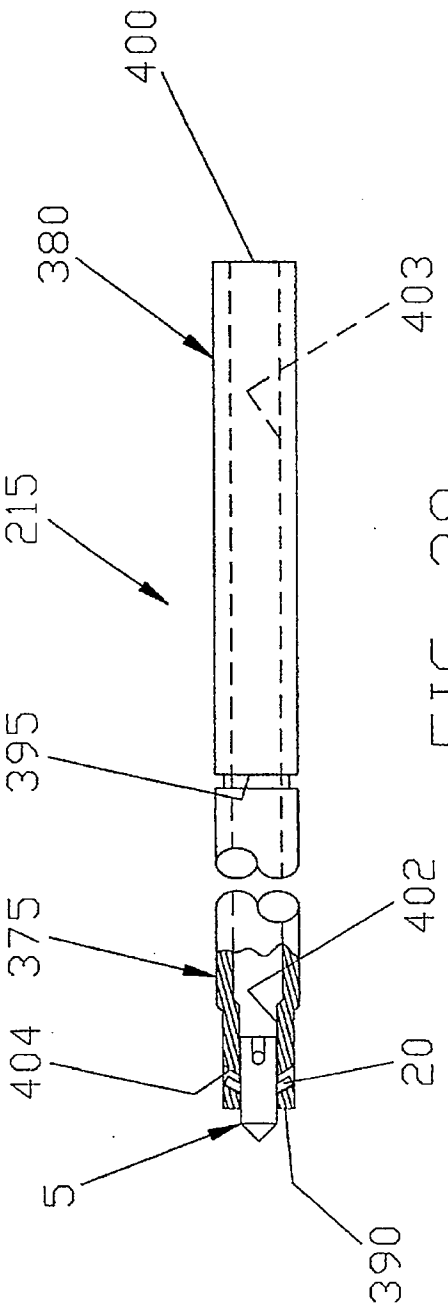
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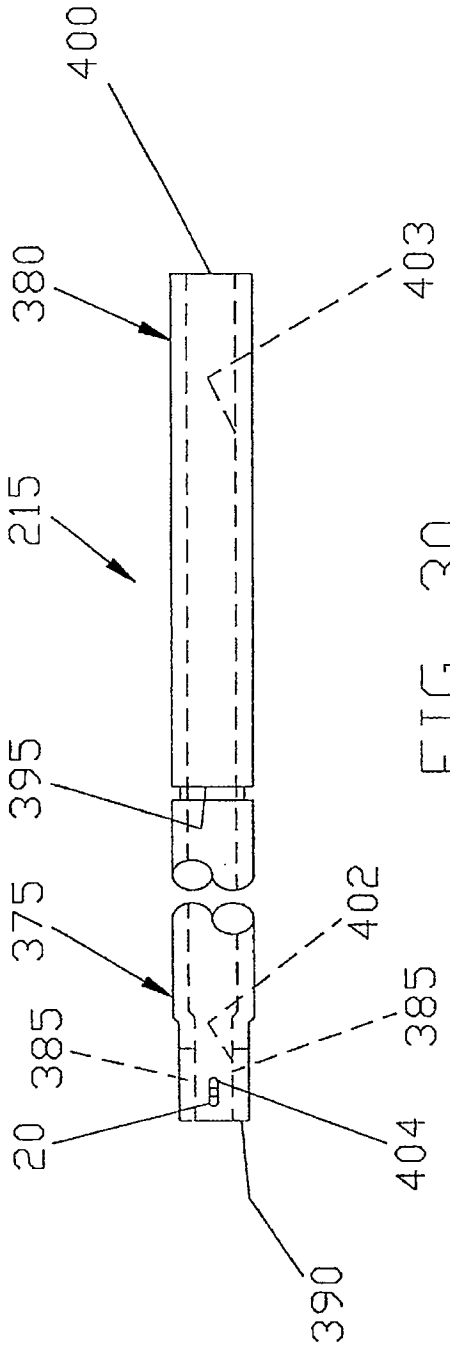
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FIG. 30

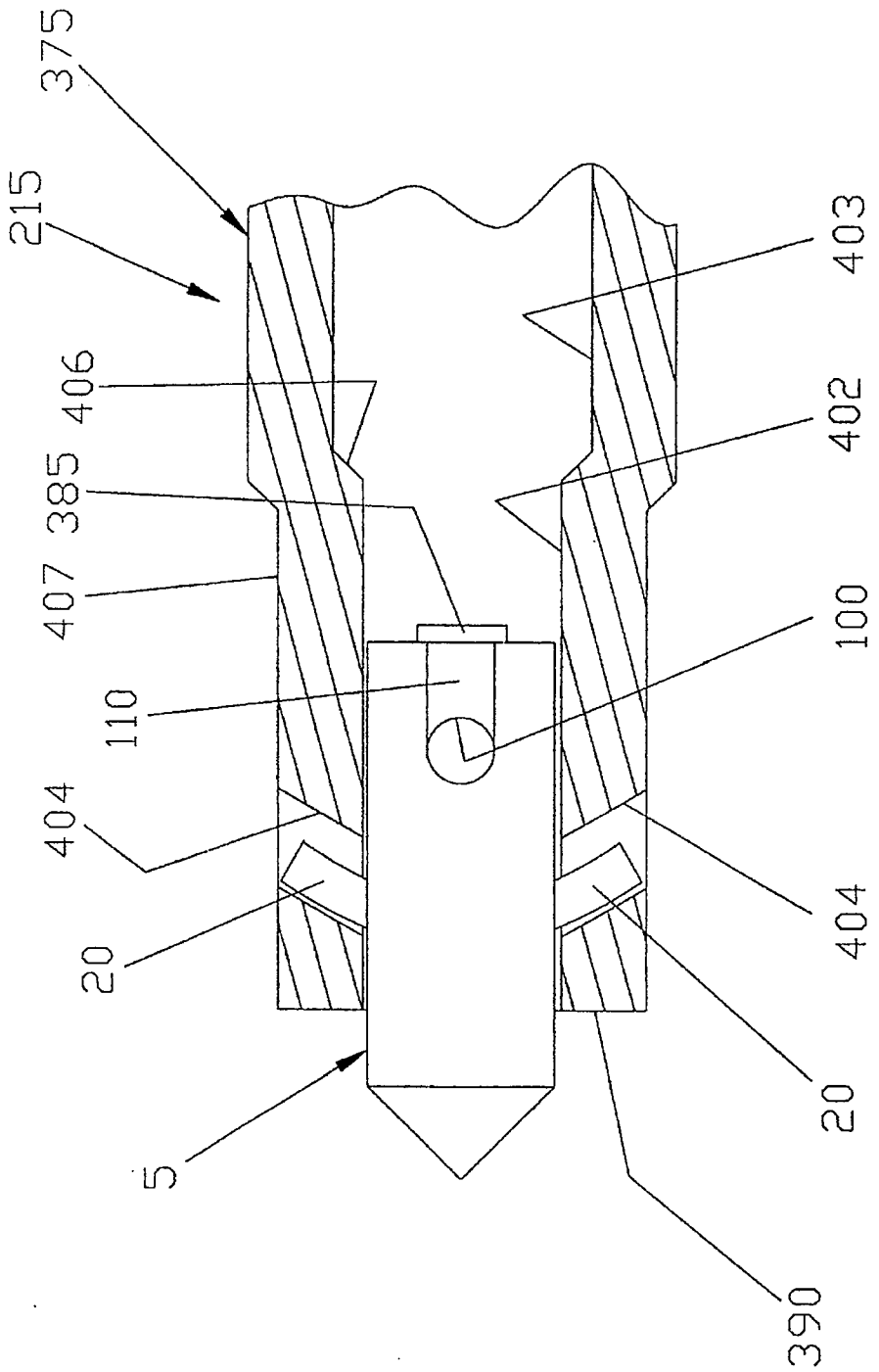

FIG. 31

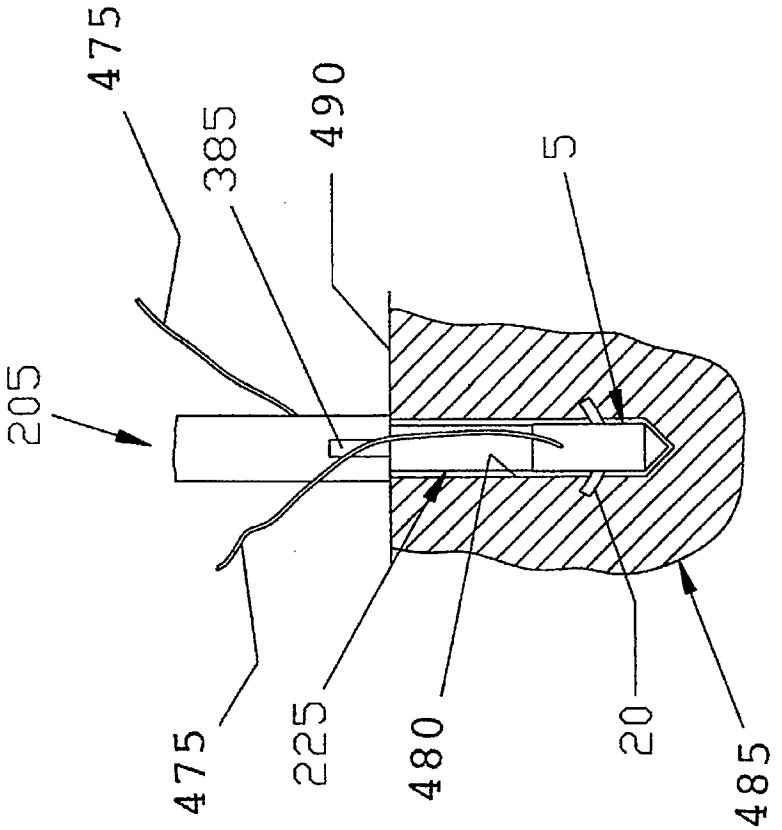

FIG. 33

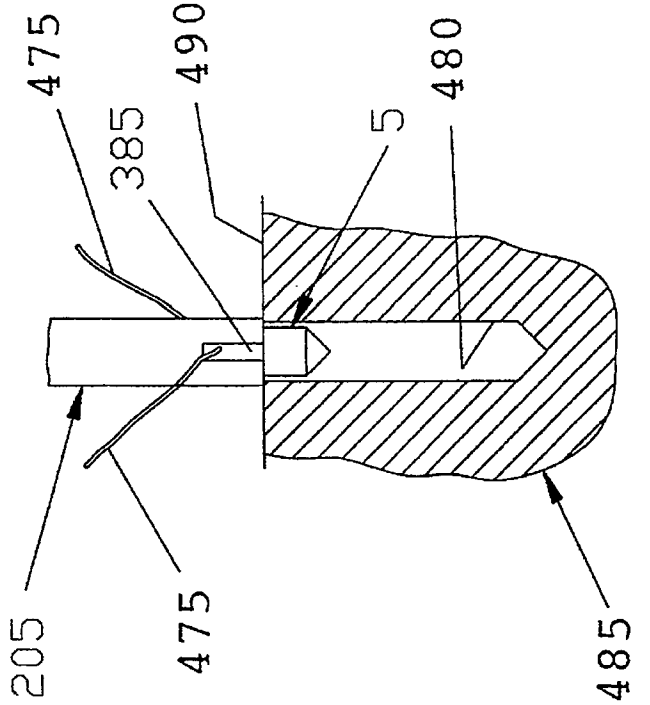

FIG. 32

BONE ANCHOR AND BONE ANCHOR INSTALLATION

FIELD OF THE INVENTION

This invention relates to surgical devices in general, and more particularly to devices for attaching suture, bone and/or soft tissue to bone.

BACKGROUND OF THE INVENTION

Bone anchors for attaching suture, bone and/or soft tissue to bone are well known in the art. See, for example, U.S. Pat. Nos. 4,898,156; 5,046,513; 5,192,303; 4,899,743; 4,968,315; 4,946,468; 5,002,550; 5,207,679; and 5,217,486; and U.S. patent applications Ser. Nos. 07/981,011; 08/075,168; 08/030,657; 08/197,927; 08/098,599; and 08/180,425.

Installation tools for deploying such bone anchors in bone are also well known in the art. See, for example, the foregoing U.S. patents and patent applications.

Complete details of the construction and operation of the foregoing exemplary bone anchors and bone anchor installation tools are provided in the above-identified patents and patent applications, which patents and patent applications are hereby incorporated herein by reference.

While the bone anchors disclosed in the foregoing U.S. patents and patent applications have proven more than satisfactory for most applications, it has been noted that certain problems can occur when using these bone anchors in special situations.

More particularly, with some of the foregoing bone anchors (e.g. the anchors disclosed in U.S. Pat. Nos. 5,207,679 and 5,217,486), it can be very difficult to form the bone anchors in a very, very small size, e.g. bone anchors having a length on the order of 3.7 millimeters or so. This is because the maximum radius of curvature which can be imparted to the anchor's barbs is limited by the characteristics of the material out of which the barbs are formed. When using pseudoelastic materials of the sort preferred for forming the barbs, this consideration can become significant as the size of the anchor is reduced to the point where the anchor has a length on the order of 3.7 millimeters or so. In particular, as one progressively reduces the size of the barb after the maximum radius of curvature has been encountered, the overall length of the barb must necessarily decrease. Accordingly, less barb material is available for secure attachment to the anchor body and/or less barb material is available for engaging the surrounding bone during anchor deployment.

Furthermore, while the bone anchor installation tools disclosed in the foregoing U.S. patents and patent applications have proven more than satisfactory for most applications, it has been noted that certain problems can occur when using these installation tools in special situations.

More particularly, with some of the foregoing installation tools (e.g. the installation tools disclosed in U.S. Pat. Nos. 4,898,156; 5,046,513; 5,192,303; and 4,899,743), the portion of the tool which carries the anchor (i) is wider than the body of the anchor itself, and (ii) must be positioned within the bone during anchor deployment. As a result of this construction, the bone hole must be formed significantly larger than the body of the anchor in order to permit anchor deployment. This can be a disadvantage in certain situations where it may be necessary to form the smallest possible hole in the bone.

With others of the foregoing installation tools (e.g. the installation tools disclosed in U.S. Pat. No. 5,217,486 and U.S. patent application Ser. No. 08/098,599), the portion of the tool which carries the anchor does not need to be received by the bone during anchor deployment. Instead, only a relatively thin drive pin enters the bone during anchor deployment. The drive pin is formed so that it has a diameter less than the diameter of the anchor body. As a result of this construction, the bone hole can be formed so that it has substantially the same width as the anchor body. However, it has also been found that where the installation tool is being used to set extremely small bone anchors, the drive pin must be so thin that it may bend or otherwise deform in certain circumstances. When this occurs, it may affect anchor deployment and/or render the installation tool unusable for subsequent anchor deployments.

In addition to the foregoing, it has also been found that where the installation tools are being used in conjunction with anchors adapted to attach suture to bone, it can be very helpful to provide suture management means for controlling the disposition of the one or more free suture ends. In this respect it is noted that with some of the foregoing installation tools (e.g. the installation tools disclosed in U.S. Pat. Nos. 4,946,468 and 5,002,550), such suture management means are provided. While such suture management means work well enough for most applications, it has been found that alternative suture management means could be helpful in some situations.

Furthermore, as the overall size of a bone anchor is decreased, it becomes less and less practical for the bone anchor to be mounted to the installation tool in the field (e.g. the operating room). Instead, it becomes necessary to mount the bone anchor in the installation tool at the point of manufacture. However, with the bone anchor installation tools of the type disclosed above, this means that the installation tool cannot easily be reused to deploy a subsequent anchor. Thus, with bone anchor installation tools of the sort disclosed above, the installation tool must generally be made so as to be disposable when it is to be used with a very, very small anchor. This can be undesirable in many circumstances.

Additionally, as the overall size of the bone anchor is decreased, it becomes more important to provide additional means for ensuring that the bone anchor does not become separated from the installation tool prior to deployment of the bone anchor in bone.

OBJECTS OF THE INVENTION

Accordingly, one object of the present invention is to provide an improved bone anchor. Another object of the present invention is to provide an improved bone anchor which can be formed in a very, very small size, e.g. on the order of 3.7 millimeters or so in length.

A further object of the present invention is to provide an improved bone anchor, wherein the bone anchor uses a new barb configuration so as to permit the bone anchor to be formed very, very small, yet provides sufficient barb material for secure attachment to the anchor body and for engaging the surrounding bone during anchor deployment.

Yet another object of the present invention is to provide an improved bone anchor of the sort adapted to anchor suture to bone.

Still another object of the present invention is to provide an improved bone anchor installation tool.

Another object of the present invention is to provide an improved bone anchor installation tool, wherein the installation tool is adapted to deploy bone anchors of the type adapted to anchor suture to bone.

A further object of the present invention is to provide an improved bone anchor installation tool, wherein the installation tool is adapted to provide improved suture management means for managing the free end or ends of a suture or sutures attached to the bone anchor.

Yet another object of the present invention is to provide an improved bone anchor installation tool, wherein the installation tool is relatively easy to manufacture and relatively inexpensive to produce.

Still another object of the present invetion is to provide an improved bone anchor installation tool, wherein the installation tool is adapted to deploy very, very small suture anchors.

Yet another object of the present invention is to provide an improved bone anchor installation tool, wherein the installation tool is adapted to permit a suture anchor to be attached to a portion of the tool at the point of manufacture, with this portion of the tool being attachable to another portion of the installation tool in the field (e.g. in the operating room).

And another object of the present invention is to provide additional means for ensuring that the bone anchor does not become separated from its seat on the installation tool prior to the deployment of the bone anchor in bone.

Still another object of the present invention is to provide a novel method for deploying a bone anchor in bone.

SUMMARY OF THE INVENTION

These and other objects of the present invention are achieved through the provision and use of a novel bone anchor and a novel bone anchor installation tool.

The novel bone anchor includes a housing, at least two barbs, and suture attachment means for attaching one or more lengths of suture to the bone anchor.

The housing has a longitudinal axis and includes a distal portion having an inner end and an outer end, and a proximal portion having an inner end and an outer end. The inner end of the distal portion is connected to the inner end of the proximal portion. The housing has a maximum cross-section, as measured transverse to its longitudinal axis, which is slightly smaller than the diameter of the hole in the workpiece within which the anchor is to be deployed. At least two equally-circumferentially-spaced longitudinal channels extend from the inner end of the proximal portion to the outer end of the proximal portion. The depth of these longitudinal channels gradually decreases as the channels extend from the inner end of the proximal portion to the outer end of the proximal portion. Each of the longitudinal channels also has an associated bore communicating therewith. Each of these bores extends from the inner end of the distal portion (where it communicates with its associated longitudinal channel) toward the outer end of the distal portion.

The bone anchor's at least two barbs extend in equally-circumferentially-spaced relation to each other, with one end of each barb being disposed in a bore and the other end of the barb being substantially radially displaced from the housing, whereby each barb will be aligned with and extend out of one longitudinal channel. Each barb is curved in its normal unstressed state, but is capable of being elastically deformed to a substantially straight configuration. More particularly, each barb comprises three distinct curves so as to assume a handlebar configuration when in its normal unstressed state. Each barb is attached to the housing by forcing half of the barb into a bore and allowing the other half of the barb to protrude out of a corresponding channel.

The suture attachment means are formed in the proximal portion of the housing. In a preferred embodiment, the suture attachment means comprise a round or elongated hole extending diametrically through the proximal portion of the housing, adjacent its outer end and through the regions of the proximal portion which are located between the longitudinal channels.

The foregoing anchor is intended to be used in conjunction with a novel installation tool.

In one form of the invention, the installation tool comprises:

a body having a distal portion and a proximal portion, the distal portion terminating in a distal end surface and the proximal portion terminating in a proximal end surface, and further wherein an axial passageway extends between the distal end surface and the proximal end surface, with the distal end of the axial passageway being sized to receive at least a portion of a bone anchor therein, and further wherein at least two lateral passageways extend through the body so as to intersect the axial passageway, whereby each of the bone anchor's barbs will be received by one of the lateral passageways when the bone anchor is disposed in the distal end of the axial passageway; and

a shaft slidably disposed in the axial passageway, the shaft terminating in a distal end surface and being adapted to move between (i) a first retracted position wherein the shaft's distal end surface is withdrawn sufficiently far into the interior of the axial passageway so as to allow at least a portion of a bone anchor to be received within the distal end of the axial passageway, and (ii) a second extended position wherein the shaft's distal end surface projects out of the distal end of the axial passageway.

The installation tool also preferably comprises suture management means for managing a free end of a suture attached to a bone anchor disposed in the distal end of the axial passageway, the suture management means comprising a recess defining a first surface and an elastomer disposed in the recess so as to yieldably engage the first surface, whereby a free end of a suture may be forced between the first surface and the elastomer and retained there until thereafter forceably withdrawn.

In another form of the invention, the installation tool comprises:

a shaft comprising a first portion having a first cross-section, a second portion having a second cross-section less than the first cross-section, a shoulder defined by the intersection of the first and second portions, a third portion having a third cross-section less than the first cross-section, and a frustoconical shoulder defined by the intersection of the first and third portions;

a shaft housing adapted to slidingly receive the shaft, the shaft housing having a proximal cylindrical portion including an annular rib positioned a predetermined distance from a proximal end thereof, a fluted finger grip, and a stem extending distally from the fluted finger grip, the stem including a threaded portion and terminating in a chamfered nose;

a shaft handle adapted to fixedly receive the proximal end of the shaft, the shaft handle comprising a slotted cylindrical portion having an inwardly facing lip dis-

posed on a distal end thereof, the slotted cylindrical portion further including four slots, each of the slots being circumferentially positioned in spaced-apart relation thereby defining four fingers adapted for gripping the annular rib of the shaft housing, a slotted flange disposed at a proximal end of the slotted cylindrical portion, the slotted flange having four slots each circumferentially disposed in spaced-apart relation, and a T-shaped post extending from a proximal surface of the slotted flange and adapted for retaining a free end of a suture, the T-shaped post comprising a central column having a hole adapted for fixedly receiving the proximal end of the shaft and a flange disposed at a proximal end of the central column, the central column extending distally from a flat inner surface of the flange;

a rubber grommet disposed around the central column and adapted to releasably hold a length of suture attached to the suture anchor;

a sleeve for slidingly receiving the shaft, the sleeve comprising a proximal end and a distal end, the proximal end including an annular groove positioned a predetermined distance from a proximal end surface thereof, and the sleeve including a pair of lateral passageways communicating with the central lumen of the sleeve adjacent the distal end, with the central lumen being of reduced diameter adjacent the distal end; and

a sleeve handle comprising a proximal portion terminating in a flat proximal end, a distal portion terminating in a rounded distal end, and a bore extending between the proximal end and the rounded distal end, the sleeve handle being adapted for slidingly receiving the sleeve, the proximal portion of the sleeve handle further including a threaded counterbore adapted for releasably fastening the threaded portion of the stem, releasable locking means for releasably engaging the annular groove formed on the proximal end of the sleeve whereby the sleeve can be releasably secured to the sleeve handle, and the sleeve handle further including finger grip depressions disposed in opposing circumferential relation thereon and adapted to receive the thumb and fingers of a user during installation of the suture anchor.

The novel bone anchor installation tool can be used in the following manner to deploy the novel bone anchor in bone. First, the suture anchor is positioned at least partially within the distal end of the sleeve's axial passageway, with the bone anchor's barbs extending out through the installation tool's lateral passageways. Then the installation tool has its shaft positioned in its first retracted position, if it is not already in this position. Next, the proximal end of the sleeve is attached to the sleeve handle, and the free end of a suture (attached to the suture anchor) is positioned between the aforementioned first surface and elastomer so as to hold it to the tool. Then the distal end of the installation tool is positioned against the top surface of a bone having a hole formed therein, with the suture anchor being aligned with the hole. Next, the installation tool's shaft is moved from its first retracted position to its second extended position so as to deploy the suture anchor in the bone. Finally, the free end of the suture is removed from between the aforementioned first surface and the elastomer.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, features and advantages of the present invention will be more fully disclosed in, or rendered obvious by, the following detailed description of the preferred embodiments of the invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

FIG. **1** is a side view in elevation of a novel bone anchor formed in accordance with the present invention;

FIG. **2** is an end view showing the distal end of the bone anchor;

FIG. **3** is an end view showing the proximal end of the bone anchor;

FIG. **4** is a side view in section, showing the anchor's housing;

FIG. **5** is an end view showing the distal end of the anchor's housing;

FIG. **6** is an end view showing the proximal end of the anchor's housing;

FIG. **7** is a side view in elevation of the anchor's housing, with the anchor having been rotated 90 degrees from the position shown in FIG. **4**;

FIG. **8** is a side view in elevation of one of the anchor's barbs;

FIG. **9** is a top view of one of the anchor's barbs;

FIG. **10** is a cross-sectional view taken along line **10**—**10** of FIG. **9**;

FIG. **11** is a side view, partially in section, showing two barbs disposed in the anchor's housing;

FIG. **12** is a side elevational view of a fully assembled installation tool formed in accordance with the present invention, wherein the installation tool's shaft is in its first retracted position;

FIG. **13** is a side elevational view of the same fully assembled installation tool, wherein the installation tool's shaft is in its second extended position;

FIG. **14** is a side elevational view, in partial section, of the installation tool's shaft subassembly;

FIG. **15** is a side elevational view, partially in section, of a sleeve which constitutes part of the installation tool;

FIG. **16** is a side elevational view of the same sleeve, but with the sleeve having been rotated 90 degrees from the position shown in FIG. **15**;

FIG. **17** is a side elevational view of a sleeve handle which constitutes part of the installation tool;

FIG. **18** is a bottom view of the sleeve handle;

FIG. **19** is an end view showing the proximal end of the sleeve handle;

FIG. **20** is a side view of a spring latch which is attached to the sleeve handle;

FIG. **21** is an end view of the distal end of the same spring latch;

FIG. **22** is a bottom view of the same spring latch;

FIG. **23** is a side elevational view of a shaft which constitutes part of the installation tool's shaft subassembly;

FIG. **24** is a side elevational view of a shaft housing which constitutes part of the installation tool's shaft subassembly;

FIG. **25** is a cross-sectional view taken along line **25**—**25** of FIG. **24**;

FIG. **26** is an end view showing the proximal end of the shaft housing;

FIG. **27** is a side view in section of a shaft handle which constitutes part of the installation tool's shaft subassembly;

FIG. **28** is an end view showing the proximal end of the shaft handle;

FIG. 29 is a side view partially in section showing a bone anchor installed in the distal end of the bone anchor installation tool of the present invention;

FIG. 30 is a side view like that of FIG. 29, except that none of the drawing is in section and the bone anchor and installation tool have been rotated 90 degrees from the positions shown in FIG. 29;

FIG. 31 is an enlarged distal end view corresponding to the view shown in FIG. 29;

FIG. 32 is a side view showing the bone anchor and bone anchor installation tool, wherein the distal end of the installation tool is in engagement with the outer surface of a bone and the bone anchor is about to be deployed in that bone; and

FIG. 33 is a view like that of FIG. 32, except that the bone anchor has been deployed in the bone.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning first to FIGS. 1–11, a bone anchor 5 is shown which generally comprises a body 10 having a longitudinal axis 15 and at least two identical barbs 20. More specifically, and looking now at FIGS. 4–7 and 11, body 10 has a distal portion 25 having an inner end 30 and an outer end 35, and a proximal portion 40 having an inner end 45 and an outer end 50. Inner end 30 of distal portion 25 is connected to inner end 45 of proximal portion 40. Body 10 has a maximum cross-section (taken transverse to longitudinal axis 15) which is only slightly smaller than the diameter of a hole formed in a target bone, as will hereinafter be disclosed in greater detail. Body 10 is preferably formed out of 6AL-4V ELI titanium, although other suitable materials may also be used.

At least two equally-circumferentially-spaced longitudinal channels 55 are formed in the exterior of body 10. Each of the longitudinal channels 55 extends from inner end 45 of proximal portion 40 to outer end 50 of proximal portion 40. In the anchor embodiment shown in the drawings, there are two such channels 55. In fact, there are always exactly as many channels 55 as there are barbs 20 on the anchor. Thus, in the embodiment shown in the drawings, inasmuch as there are two barbs 20 on body 10, there are also two channels 55. The floors 60 of channels 55 slant outwardly relative to the anchor's longitudinal axis 15 at an angle of between about 12 and 30 degrees. Longitudinal channels 55 extend all the way to, and open on, outer end 65 of proximal portion 40.

At least two longitudinal bores 70 extend through distal portion 25, parallel to longitudinal axis 15. Bores 70 communicate with channels 55. In the embodiment shown, there are two such bores 70. In fact, there are always exactly as many of these bores 70 as there are barbs 20 on the anchor, and hence exactly as many of these bores 70 as there are channels 55. One bore 70 communicates with each channel 55, so as to form a forward extension of that channel.

Looking next at FIGS. 1–3 and 8–11, barbs 20 are each formed from a curved length of wire having a first or inner end 75 and a second or outer end 80. Barbs 20 are formed out of a relatively strong, highly elastic material such as a pseudoelastic alloy. Preferably barbs 20 are formed out of a stress induced martensite (SIM) shape memory alloy (SMA) material. Such materials are readily available from Raychem Corporation of Menlo Park, Calif. and Shape Memory Applications, Inc. of Sunnyvale, Calif. among others. The first or inner ends 75 of barbs 20 are attached to the anchor's distal portion 25 so that the barbs extend axially and radially outward therefrom. Each barb 20 is capable of being elastically deformed to a substantially straight configuration when desired.

More particularly, each barb 20 comprises three distinct curves 85, 90 and 95 (FIG. 8) so as to assume a handlebar configuration in its normal unstressed state. Each barb 20 is attached to body 10 by forcing half of the barb into a bore 70 and allowing the remaining half of the barb to protrude out of a corresponding channel 55 (FIG. 11). The tendency of curved barbs 20 to return to their natural configuration after insertion into the straight bores 70 acts to securely hold the barbs in position within bores 70. The permanence of this engagement may be further assured by crimping distal portion 25 inwardly adjacent bores 70, or otherwise mechanically locking in place the portions of barbs 20 inserted into bores 70.

In view of the foregoing construction, it will be seen that barbs 20 will normally project axially rearward and radially outward from body 10, but they may also be bent inwardly under sufficient forces so that they can lie substantially flat against floors 60 of channels 55.

In this respect it is to be appreciated that barbs 20 and channels 55 are also sized and positioned relative to one another so that when barbs 20 are forced inwardly so as to lie against channel floors 60, all but the outermost portions 80 of barbs 20 will reside inside channels 55. Due to the inclined geometry of floors 60 at the proximal end of body 10, however, the outermost portions 80 of barbs 20 will remain at least slightly outboard of anchor body 10 even when barbs 20 lie against channel floors 60.

It is to be appreciated that, by forming barbs 20 with the foregoing handlebar configuration, the barbs will provide sufficient barb material for secure attachment to the anchor housing, and sufficient barb material for engaging the surrounding bone during anchor deployment, even when the anchor is formed with a very small size, e.g. with a body having a length on the order of 3.7 millimeters or so.

Still looking now at FIGS. 1–11, suture attachment means 100 are provided at proximal portion 40 of the anchor body. In the embodiment shown, suture attachment means 100 comprise a bore which extends through body 10, transverse to longitudinal axis 15 and between slanted floors 60 of channels 55 and adjacent to outer end 65 of proximal portion 40. The portion of bore 100 closest to outer end 65 of proximal portion 40 forms a smoothly contoured bearing surface 105 (FIG. 7) such that no sharp edges will be presented to a length of suture threaded through bore 100 and engaging surface 105, and such that a length of suture threaded through bore 100 and engaging surface 105 may be slid along that bearing surface 105 if desired after anchor 5 has been deployed in a bone hole. In addition, indented portions 110 (FIGS. 3, 6 and 7) preferably connect the proximal end of bore 100 to outer end 65 of proximal portion 40, thereby providing a protected pathway for the suture to emerge from bore 100 and extend proximally of the suture anchor.

It will be appreciated that by placing attachment means 100 at the proximal end of anchor 5 and locating attachment means 100 on the longitudinal axis of the anchor, any forces applied to the free ends of the suture once the suture anchor has been set in bone will not tend to induce rotational torque upon the anchor.

It is also to be appreciated that by inclining floors 60 of channels 55 at the proximal end of anchor body 10, sufficient body material will be provided about bore 100 so as to ensure the structural integrity of suture attachment means 100, while still allowing anchor 5 to be formed with the narrowest possible body diameter.

Looking next at FIGS. 12 and 13, a bone anchor installation tool 205 is shown which comprises a preferred embodiment of the present invention. Installation tool 205 generally comprises a shaft subassembly 210 (FIGS. 12–14), a sleeve 215 (FIGS. 12, 13, 15 and 16) and a sleeve handle 220 (FIGS. 12, 13 and 17–19).

More particularly, and looking now at FIG. 14, shaft subassembly 210 generally comprises a shaft 225, a shaft housing 230, a shaft handle 235 and a rubber grommet 237.

Shaft 225 is shown in greater detail in FIG. 23. Shaft 225 comprises a first cylindrical portion 240 and a second cylindrical portion 245. Second cylindrical portion 245 has a smaller diameter than first cylindrical portion 240. First cylindrical portion 240 and second cylindrical portion 245 together define an annular shoulder 250. First cylindrical portion 240 is connected to a third cylindrical portion 251. Third cylindrical surface 251 has a smaller diameter than first cylindrical portion 240. First cylindrical portion 240 and third cylindrical portion 251 together define a frusto-conical section 252. Third cylindrical portion 251 terminates in a distal end surface 255. Second cylindrical portion 245 terminates in a proximal end surface 260. Shaft 225 is formed so that the relatively thin third cylindrical portion 251 has a relatively short length relative to the remainder of the shaft.

Shaft housing 230 is shown in greater detail in FIGS. 24–26. Shaft housing 230 comprises a fluted finger grip 265 having a flat distal surface 267. A stem 270 extends distally away from the fluted finger grip's flat distal surface 267. Stem 270 includes a threaded portion 275 and terminates in a chamfered distal nose 280. Shaft housing 230 also comprises a cylindrical portion 285 extending proximally away from fluted finger grip 265. Cylindrical portion 285 includes an annular rib 290 and terminates in a flat proximal end surface 295. A central passageway 300 extends through shaft housing 230, from chamfered distal nose 280 of stem 270 to flat proximal end surface 295 of cylindrical portion 285.

Shaft handle 235 is shown in greater detail in FIGS. 27 and 28. Shaft handle 235 comprises a slotted cylindrical portion 305, a slotted flange 310 and a T-shaped post 315. More particularly, slotted cylindrical portion 305 comprises an inwardly facing lip 325 and four slots 330. Slots 330 are disposed in equally-circumferentially-spaced relation about the circumference of slotted cylindrical portion 305. In essence, slots 330 divide slotted cylindrical portion 305 into four longitudinally-extending fingers. Slotted flange 310 comprises four slots 335. Slots 335 are disposed in equally-circumferentially-spaced relation about the circumference of slotted flange 310. Slots 335 of slotted flange 310 are aligned with slots 330 of slotted cylindrical portion 305. Slotted flange 310 terminates in a flat distal surface 337 and in a proximal surface 340. The flange's proximal surface 340 is preferably rounded somewhat at its circumferential edge 342, adjacent to where proximal surface 340 meets flat distal surface 337. T-shaped post 315 comprises a cylindrical central column 345 and an annular flange 350. Flange 350 terminates in a rounded proximal surface 355 and in a flat distal surface 360. A rounded circumferential edge 365 is defined by the intersection of rounded proximal surface 355 and flat distal surface 360. A hole 370 extends axially through slotted flange 310 and into T-shaped post 315, and communicates with the interior of slotted cylindrical portion 305. Hole 370 is coaxial with, and communicates with, another hole 371 which opens on rounded proximal surface 355.

Rubber grommet 237 (FIGS. 12–14) comprises a toroidal shaped piece of elastomer adapted to be positioned on shaft handle 235. More particularly, rubber grommet 237 is adapted to be fit over the shaft handle's cylindrical central column 345 so as to be compressed between flat proximal surface 340 of slotted flange 310 and flat distal surface 360 of annular flange 350.

Shaft subassembly 210 is assembled as follows. First, the shaft's second portion 245 is passed through the shaft housing's central passageway 300 until the shaft housing's chamfered distal nose 280 engages the shaft's annular shoulder 250. Then shaft handle 235 is passed over the proximal end of shaft housing 230 until the proximal end of shaft 225 enters the shaft handle's hole 370. The proximal end of shaft 225 is then made fast in hole 370 by welding, using access hole 371. On account of the foregoing construction, shaft 225 and shaft handle 235 thereafter operate as a single unit, with shaft housing 230 being slidably captured on shaft 225 between the shaft's annular shoulder 250 and the shaft handle's distal surface 337, as will hereinafter be described in further detail. Once this has been accomplished, rubber grommet 237 is then mounted onto the shaft handle's cylindrical central column 345.

Looking next at FIGS. 15, 16 and 29–31, sleeve 215 comprises a distal portion 375 and a proximal portion 380. Distal portion 375 comprises two slots 385. Slots 385 are equally-circumferentially-spaced about the circumference of sleeve 215. Slots 385 open on the sleeve's distal end surface 390. The proximal portion of sleeve 215 includes an annular groove 395 and terminates in a proximal end surface 400. A bore 402 opens on distal end surface 390 and a coaxial counterbore 403 opens on proximal end surface 400. Bore 402 and counterbore 403 meet at an annular shoulder 406. Bore 402 is sized so that the shaft's third cylindrical portion 251 will make a close sliding fit within bore 402, and counterbore 403 is sized so that the shaft's first cylindrical portion 240 will make a close sliding fit within counterbore 403. Two lateral passageways 404 are formed in distal portion 375. Passageways 404 are equally-circumferentially-spaced about the circumference of sleeve 215. Passageways 404 extend at an acute angle to the longitudinal axis of sleeve 215 and communicate with bore 402. Preferably, the distal end of sleeve 215 is relieved slightly about its outer surface as shown at 407 so as to improve visibility at the surgical site.

Looking next at FIGS. 17–19, sleeve handle 220 comprises a distal portion 405 and a proximal portion 410. Distal portion 405 terminates in a rounded distal end surface 415 and proximal portion 410 terminates in a flat proximal end surface 420. Sleeve handle 220 also includes a bore 425 and a proximal counterbore 430. Counterbore 430 opens on the sleeve handle's flat proximal end surface 420. Bore 425 and counterbore 430 meet at an internal angled shoulder 435. The proximal portion of counterbore 430 is threaded at 440. A plurality of finger grip depressions 445 are formed in the outer surface of sleeve handle 220.

Sleeve handle 220 also includes a distal counterbore 448, a bottom recess 451, a threaded blind hole 454 extending upward into the body of sleeve handle 220 from bottom recess 451, and a thin slot 457 extending upward into the body of sleeve handle 220 from bottom recess 451. Counterbore 448 is coaxial with bore 425 and opens on rounded distal end surface 415. A spring latch 460 (FIGS. 12, 13 and 20–22) is disposed in bottom recess 451 so that its vertical leg 463 extends upward into thin slot 457 and its horizontal leg 466 extends along bottom recess 451, with the horizontal leg's hole 469 aligned with the sleeve handle's threaded blind hole 454. A screw (not shown) extends through the spring latch's hole 469 and into threaded blind hole 454 so

as to attach the spring latch to the sleeve handle. The spring latch includes an elliptical opening **472** in its vertical leg **463** which intrudes across the sleeve handle's counterbore **448**, whereby the spring latch can act as a releasable locking means for releasably capturing sleeve **215** to the sleeve handle, as will hereinafter be described in further detail.

The complete bone anchor installation tool **205** is assembled as follows. First, the assembled shaft subassembly **210** is passed distal end first through counterbore **430**, bore **425** and counterbore **448** of sleeve handle **220**, until chamfered distal nose **280** of shaft subassembly **210** enters counterbore **430** of sleeve handle **220**. Shaft subassembly **210** is then rotated so that the shaft housing's threaded portion **275** engages threads **440** of sleeve handle **220**. Shaft subassembly **210** is turned until the shaft housing's flat distal surface **267** engages the sleeve handle's proximal end surface **420**.

Once shaft subassembly **210** has been connected to sleeve handle **220** in the foregoing manner, sleeve **215** can be connected to sleeve handle **220**. This is done by depressing spring latch **460** so as to align its elliptical opening **472** with the sleeve handle's counterbore **448**, and then passing the proximal end of sleeve **215** into the distal end of sleeve handle **220**. Spring latch **460** can thereafter be released to engage the sleeve's annular groove **395** and thereby releasably bind sleeve **215** to the remainder of the installation tool.

When bone anchor installation tool **205** is assembled in the foregoing manner, its shaft **225** will be free to move between (i) a first retracted position (FIG. **12**) wherein the shaft's annular shoulder **250** is substantially in engagement with the shaft housing's chamfered distal nose **280**, and the shaft handle's inwardly facing lip **325** is on the proximal side of, and substantially in engagement with, the shaft housing's annular rib **290**, and the shaft's distal end surface **255** is withdrawn into the interior of sleeve **215**; and (ii) a second extended position (FIG. **13**) wherein the shaft handle's flat distal end surface **337** is in engagement with the shaft housing's flat proximal end surface **295**, and the shaft handle's inwardly facing lip **325** is on the distal side of, and substantially displaced from, the shaft housing's annular rib **290**, and the shaft's distal end surface **255** protrudes a substantial distance beyond the sleeve's distal end surface **390**.

Bone anchor installation tool **205** is preferably used to deploy a suture anchor such as the suture anchor **5** disclosed above, or a suture anchor of the sort disclosed in the aforementioned U.S. Pat. No. 5,217,486 and/or a suture anchor of the sort disclosed in the aforementioned U.S. patent application Ser. No. 08/197,927, i.e., bone anchor installation tool **205** is preferably used to deploy a suture anchor of the sort comprising (i) a generally cylindrical body, (ii) a pair of flexible barbs extending laterally out of the side of the body, and (iii) suture attachment means for attaching a length of suture to the body. Of course, bone anchor installation tool **205** may also be used to deploy other types of bone anchors in bone or other types of fasteners in a workpiece, so long as such bone anchor or fastener is compatible with the present invention.

Bone anchor **5** and bone anchor installation tool **205** are intended to be used as follows. First, installation tool **205** is assembled so that its complete shaft subassembly **210** is connected to its sleeve handle **220**, but without any sleeve **215** being connected to the sleeve handle. Then a bone anchor **5** is loaded into the proximal end of sleeve **215** and forced down the length of the sleeve until its barbs **20** project into lateral passageways **404** and its suture hole **100** is aligned with slots **385** (FIGS. **29–31**). In this respect, it will be appreciated that the nature of the fit of barbs **20** in lateral passageways **404** will tend to keep anchor **5** from unintentionally separating from sleeve **215**. A suture **475** (FIG. **32**) is then threaded through slots **385** and suture hole **100** so as to connect suture **475** to the suture anchor.

Next, shaft **225** is positioned so that it is in its aforementioned first retracted position, wherein the shaft's annular shoulder **250** is substantially in engagement with the shaft housing's chamfered distal nose **280**, and the shaft handle's inwardly facing lip **325** is on the proximal side of, and substantially in engagement with, the shaft housing's annular rib **290**. Then a sleeve **215** (carrying a suture anchor **5** therein) is secured to sleeve handle **220** by depressing spring latch **460**, inserting the proximal end of the sleeve into sleeve handle **220**, and then releasing the spring latch. At this point the shaft's distal end surface **255** will reside within the interior of sleeve **215** (FIG. **12**). It is to be appreciated that bone anchor installation tool **205** will be inclined to remain in its aforementioned first retracted position until it is thereafter forced to assume another position, inasmuch as the shaft housing's annular rib **290** will tend to inhibit passage of the shaft handle's inwardly facing lip **325**.

Next, the two lengths of suture **475** are extended tautly back along the length of the installation tool and threaded through one or more of the shaft handle's slots **335** before being wound tightly around the shaft handle's cylindrical central column **345**, in the space between rubber grommet **237** and the shaft handle's surface **340**. The resilient engagement of rubber grommet **237** with the shaft's surface **340** thereafter serves to keep the two lengths of suture **475** securely in place at the proximal end of the installation tool, yet allows a surgeon to easily pull the two lengths of suture free from the installation tool when needed. Next, and looking now at FIG. **32**, the installation tool is manipulated so as to position the distal portion of suture anchor **5** within the top of a hole **480** formed in a bone **485**, with the distal end of sleeve **215** engaging the top surface **490** of the bone.

Suture anchor **5** can then be deployed in bone **485** by pressing on the shaft handle's proximal surface **355** so as to urge the installation tool's shaft **225** into its aforementioned second extended position. As this occurs, the shaft handle's inwardly facing lip **325** will be forced over the shaft housing's annular rib **290** as the shaft handle's flat distal end surface **337** moves into engagement with the shaft housing's flat proximal end surface **295** and the shaft's distal end surface **255** moves out of the sleeve's distal end. As a consequence of this action, suture anchor **5** will be driven out of the distal end of sleeve **215** and into bone **485**, with the suture anchor's barbs **20** securing the anchor in place within the bone and with the two lengths of suture **475** extending back out of the bone hole to the installation tool. In this respect it will be appreciated that the relatively close fit between the shaft's third cylindrical portion **251** and the sleeve's bore **402**, as well as the relatively short length of third cylindrical portion **251**, will tend to ensure that the relatively thin third cylindrical portion of shaft **225** does not deform during anchor deployment. The two lengths of suture **475** may then be unwound from the installation tool before the installation tool is removed from the surgical site.

Another bone anchor may thereafter be deployed by the installation tool simply by dismounting sleeve **215** from sleeve handle **220** via spring latch **460**, returning shaft **225** to its aforementioned first retracted position, and then repeating the aforementioned process, i.e., mounting a sleeve **215** (carrying a suture anchor **5** thereon) to the tool, etc.

In view of the very tiny nature of the bone anchors **5**, it is envisioned that bone anchors **5** will be loaded on sleeves **215** at the point of manufacture, and then sleeves **215** (and their associated bone anchors) will be attached to the remainder of the installation tool in the field (e.g. in an operating room).

Advantages of the Present Invention

Numerous advantages are obtained by using the present invention.

For one thing, an improved bone anchor is provided.

For another thing, an improved bone anchor is provided which can be formed in a very, very small size.

Also, an improved bone anchor is provided which uses a new barb configuration so as to permit the bone anchor to be formed very, very small, yet provides sufficient barb material for secure attachment to the anchor body and for engaging the surrounding bone during anchor deployment.

Furthermore, an improved bone anchor is provided which is adapted to anchor suture to bone.

Also, an improved bone anchor installation tool is provided.

And an improved bone anchor installation tool is provided, wherein the installation tool is adapted to deploy bone anchors of the type adapted to anchor suture to bone.

Also, an improved bone anchor installation tool is provided, wherein the installation tool is adapted to provide improved suture management means for managing the free end or ends of a suture or sutures attached to the bone anchor.

Furthermore, an improved bone anchor installation tool is provided, wherein the installation tool is relatively easy to manufacture and relatively inexpensive to produce.

In addition, an improved method is provided for deploying a bone anchor in bone.

Still other advantages of the invention will be obvious to those skilled in the art.

Modifications of the Preferred Embodiment

It will, of course, be appreciated that certain modifications may be made to the foregoing preferred embodiment of the present invention without departing from the scope of the present invention.

Thus, for example, more than two slots **385** may be provided in the distal end of sleeve **215**, where the installation tool is to be used in conjunction with a bone anchor of the sort having more than two free suture ends.

Furthermore, more or less than four slots **330** may be provided in slotted cylindrical portion **305**, and/or more or less than four slots **335** may be provided in slotted flange **310**.

Also, fluted finger grip **265** could be formed with an exterior surface which is knurled rather than fluted, or finger grip **265** could be formed with a relatively smooth surface if desired.

Additionally, suture could be held to the proximal end of the installation tool by wrapping it around cylindrical central column **345** between rubber grommet **237** and the shaft handle's flat surface **360**, rather than between rubber grommet **237** and the shaft handle's surface **340**.

These and other changes will be obvious to a person skilled in the art, and are considered to be within the scope of the present invention.

What is claimed is:

1. A bone anchor for attaching suture to a bone, said bone anchor comprising a body, at least two barbs fixed to said body, and suture attachment means on said body,

said body having a longitudinal axis, a distal portion having an inner end and an outer end, and a proximal portion having an inner end and an outer end, wherein said inner end of said distal portion is connected to said inner end of said proximal portion;

said body further comprising at least two equally-circumferentially-spaced longitudinal channels extending from said inner end of said proximal portion to said outer end of said proximal portion, with the depth of said longitudinal channels gradually decreasing as said channels extend from said inner end of said proximal portion to said outer end of said proximal portion, and further wherein each of said longitudinal channels also has an associated bore communicating therewith, said bores extending from said inner end of said distal portion toward said outer end of said distal portion;

said barbs extending in equally-circumferentially-spaced relation to each other, and in equally spaced radial relation to the longitudinal axis, with one end of each of said barbs being disposed in one of said bores and the other end of said barb being substantially radially displaced from said housing, whereby each of said barbs is aligned with and extends out of one of said longitudinal channels, with each of said barbs being curved in its unstressed state, but being capable of being elastically deformed to a substantially straight configuration;

wherein each barb comprises three distinct curves so as to assume a handlebar configuration when it is in said unstressed state, with each of said barbs being attached to said body by positioning half of said barb in one of said bores with the other half of said barb protruding out of a corresponding one of said longitudinal channels; and

said suture attachment means are formed in said proximal portion of said body and comprise a hole extending diametrically through said proximal portion of said body.

2. An installation tool for deploying a bone anchor in bone, said installation tool comprising:

a body having a distal portion and a proximal portion, said distal portion terminating in a distal end surface and said proximal portion terminating in a proximal end surface, and further wherein an axial passageway extends between said distal end surface and said proximal end surface, with said distal end of said axial passageway being sized to receive at least a portion of a bone anchor therein, and further wherein at least two lateral passageways extend through said body so as to intersect said axial passageway, each of said lateral passageways being adapted to receive a barb extending from said bone anchor when said bone anchor is disposed in said distal end of said passageway; and

a shaft slidably disposed in said axial passageway, said shaft terminating in a distal end surface and being adapted to move between (i) a first retracted position wherein said distal end surface of said shaft is withdrawn sufficiently into the interior of said axial passageway so as to allow at least a portion of a bone anchor to be received within said distal end of said axial passageway, and (ii) a second extended position wherein said distal end surface of said shaft projects out of said distal end of said axial passageway.

3. An installation tool according to claim **2** wherein said installation tool further comprises suture management means for managing a free end of a suture attached to said bone anchor disposed in said distal end of said axial passageway, said suture management means comprising a

recess in said tool defining a first surface, and an elastomer disposed in said recess to yieldably engage said first surface, whereby to cooperatively receive the free end of the suture between said first surface and said elastomer and retain the free end of the suture until it is forceably withdrawn.

4. An installation tool for deploying a bone anchor, said installation tool comprising:

a shaft comprising a first portion having a first cross-section, a second portion having a second cross-section less than said first cross-section, a shoulder defined by the intersection of said first and said second portions, a third portion having a third cross-section less than said first cross-section, and a frustoconical shoulder defined by the intersection of said first and third portions;

a shaft housing adapted to slidingly receive said shaft, said shaft housing having a proximal cylindrical portion including an annular rib positioned a predetermined distance from a proximal end thereof, a fluted finger grip, and a stem extending distally from said fluted finger grip, said stem including a threaded portion and terminating in a chamfered nose;

a shaft handle adapted to fixedly receive a proximal end of said shaft, said shaft handle comprising a slotted cylindrical portion having an inwardly facing lip disposed on a distal end thereof, said slotted cylindrical portion further including four slots, each of said slots being circumferentially positioned in spaced-apart relation thereby defining four fingers adapted for gripping said annular rib of said shaft housing, a slotted flange disposed at a proximal end of said slotted cylindrical portion, said slotted flange having four slots each circumferentially disposed in spaced-apart relation, and a T-shaped post extending from a proximal surface of said slotted flange and adapted for retaining a free end of a suture, said T-shaped post comprising a central column having a hole adapted for fixedly receiving said proximal end of said shaft and a second flange disposed at a proximal end of said central column, said central column extending distally from a flat inner surface of said second flange;

a rubber grommet disposed around said central column and adapted to releasably hold a length of suture attached to said suture anchor;

a sleeve for slidably receiving said shaft, said sleeve comprising a proximal end and a distal end, said proximal end including an annular groove positioned a predetermined distance from a proximal end surface, and said sleeve including a pair of lateral passageways communicating with the central lumen of said sleeve adjacent the distal end, with said central lumen being of reduced diameter adjacent said distal end; and

a sleeve handle comprising a proximal portion terminating in a flat proximal end, a distal portion terminating in a rounded distal end, and a bore extending between said proximal end and said rounded distal end, said sleeve handle being adapted for slidingly receiving said sleeve, said proximal portion of said sleeve handle further including a threaded counterbore adapted for releasably fastening said threaded portion of said stem, releasable locking means for releasably engaging said annular groove formed on said proximal end of said sleeve whereby said sleeve can be releasably secured to said sleeve handle, and said sleeve handle further including finger grip depressions disposed in opposing circumferential relation thereon and adapted to receive a thumb and fingers of a user during installation of said suture anchor.

5. An installation tool according to claim 4 wherein said shaft's first and second cross-sections are cylindrical.

6. An installation tool according to claim 4 wherein said fluted finger grip comprises a plurality of circumferentially disposed flutes.

7. An installation tool according to claim 4 wherein four slots are circumferentially positioned in spaced-apart relation in said slotted flange and are in aligned relation to said slots in said slotted cylindrical portion of said shaft handle.

8. An installation tool according to claim 4 wherein said second flange of said shaft handle further comprises a rounded proximal surface and a flat distal surface so as to define a rounded circumferential edge therebetween.

9. An installation tool according to claim 4 wherein said proximal end of said shaft is welded in said hole of said shaft handle.

10. A system for deploying a suture anchor in a hole formed in a bone, said system comprising:

(i) a suture anchor comprising a generally cylindrical body, a pair of flexible barbs extending laterally out of the side of said body, and suture attachment means disposed on said body for attaching a length of suture to said body; and

(ii) an installation tool for deploying said suture anchor in bone, said installation tool comprising:

a body having a distal portion and a proximal portion, said distal portion terminating in a distal end surface and said proximal portion terminating in a proximal end surface, and further wherein an axial passageway extends between said distal end surface and said proximal end surface, with a distal end of said axial passageway being sized to receive therein at least a portion of said suture anchor, and further wherein at least two lateral passageways extend through said tool body so as to intersect said axial passageway, whereby each of said barbs is received by one of said lateral passageways when said bone anchor is disposed in said distal end of said passageway;

a shaft slidably disposed in said axial passageway, said shaft terminating in a distal end surface and being adapted to move between (i) a first retracted position wherein said distal end surface of said shaft is withdrawn sufficiently into the interior of said axial passageway to allow at least a portion of said suture anchor to be received within said distal end of said axial passageway, and (ii) a second extended position wherein said distal end surface of said shaft projects out of said distal end of said axial passageway; and

suture management means for managing a free end of a suture attached to said suture anchor when said suture anchor is disposed in said distal end of said axial passageway, said suture management means comprising a recess in said tool defining a first surface, and an elastomer disposed in said recess so as to yieldably engage said first surface, whereby to cooperatively receive a free end of the suture between said first surface and said elastomer and retain the free end of the suture until it is forceably withdrawn.

11. A method for deploying a suture anchor in bone, said method comprising the steps of:

(1) providing a system for deploying a suture anchor in a hole formed in a bone, said system comprising:

(i) a suture anchor comprising a generally cylindrical body, a pair of flexible barbs extending laterally out of the side of said body, and suture attachment means for attaching a length of suture to said body; and

(ii) an installation tool for deploying said suture anchor in bone, said installation tool comprising:

a body having a distal portion and a proximal portion, said distal portion terminating in a distal end surface and said proximal portion terminating in a proximal end surface, and further wherein an axial passageway extends between said distal end surface and said proximal end surface, with a distal end of said axial passageway being sized to receive therein at least a portion of said suture anchor, and further wherein at least two passageways extend through said tool body so as to intersect said axial passageway, whereby each of said barbs of said suture anchor is received by one of said lateral passageways when said suture anchor is disposed in said distal end of said passageway;

a shaft slidably disposed in said axial passageway, said shaft terminating in a distal end surface and being adapted to move between (i) a first retracted position wherein said distal end surface of said shaft is withdrawn sufficiently into the interior of said axial passageway to allow at least a portion of said suture anchor to be received within said distal end of said axial passageway, and (ii) a second extended position wherein said distal end surface of said shaft projects out of said distal end of said axial passageway; and

suture management means for managing a free end of a suture attached to said suture anchor when said suture anchor is disposed in said distal end of said axial passageway, said suture management means comprising a recess in said tool defining a first surface, and an elastomer disposed in said recess so as to yieldably engage said first surface, whereby to cooperatively receive a free end of the suture and retain the free end of the suture until it is forceably withdrawn;

(2) positioning said shaft in said first retracted position;

(3) positioning a suture anchor at least partially within said distal end of said axial passageway, and positioning the free end of a suture attached to said suture anchor between said first surface and said elastomer;

(4) positioning said distal end of said installation tool against a top surface of a bone having a hole formed therein, with said suture anchor being aligned with said hole;

(5) moving said shaft from said first retracted position to said second extended position so as to deploy said suture anchor in said bone; and

(6) removing said free end of said suture from between said first surface and said elastomer.

* * * * *

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United States Patent [19]

Lorenc

[11] Patent Number: 5,611,814

[45] Date of Patent: Mar. 18, 1997

[54] **RESORBABLE SURGICAL APPLIANCES AND ENDOSCOPIC SOFT TISSUE SUSPENSION PROCEDURE**

[76] Inventor: **Z. Paul Lorenc**, 52 East End Ave., Apt. 35A, New York, N.Y. 10028

[21] Appl. No.: **340,710**

[22] Filed: **Nov. 16, 1994**

[51] **Int. Cl.**[6] **A61B 17/08**

[52] **U.S. Cl.** **606/213**; 606/151; 606/204.35; 128/898

[58] **Field of Search** 606/1, 61, 72, 606/73, 77, 151, 191, 204.35, 212, 215, 216, 218, 219, 230, 232, 139; 411/388, 398, 400, 401, 907, 908; 128/898

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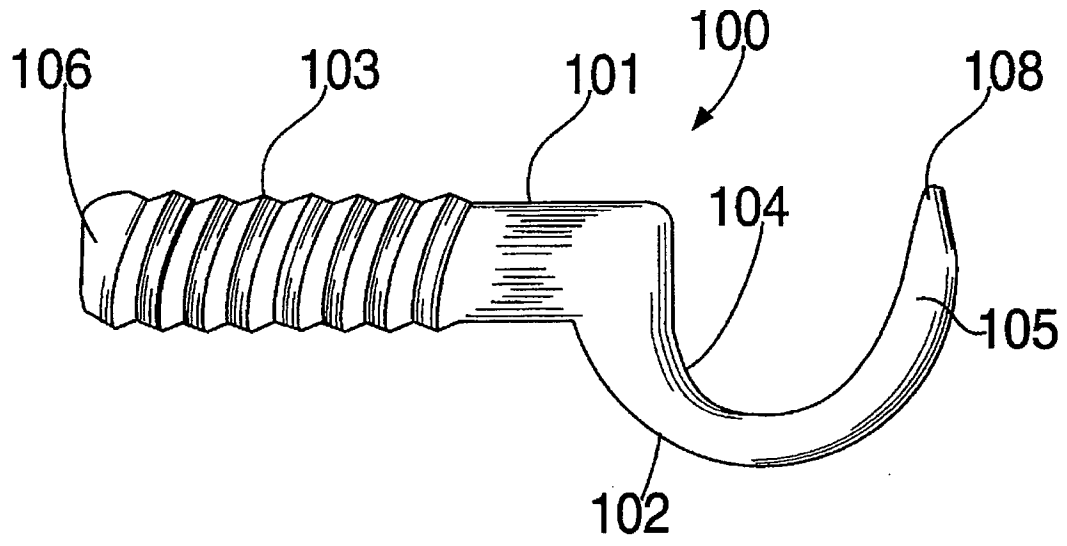
Primary Examiner—Michael Powell Buiz
Assistant Examiner—Patrick W. Rasche
Attorney, Agent, or Firm—Aufrichtig Stein & Aufrichtig, P.C.

[57] **ABSTRACT**

A resorbable surgical appliance for use in supporting soft tissue in a superior position in the body. The surgical appliance includes a coupling member that connects the surgical appliance to a bone or hard tissue and a gripping member or members secured to the coupling member selectively gripping soft tissue and retaining the soft tissue in a superior position. The connected coupling member and gripping member are formed from a resorbable mixture which maintains a specified percentage of the connection strength with the bone or hard tissue for a period of time at least equal to a healing period. Thereafter, the surgical appliance is substantially resorbed by the body over a period of time created for healing. The surgical appliance is particularly adapted for use in endoscopic brow lift surgery and other endoscopic cosmetic, plastic and reconstructive surgical procedures.

9 Claims, 3 Drawing Sheets



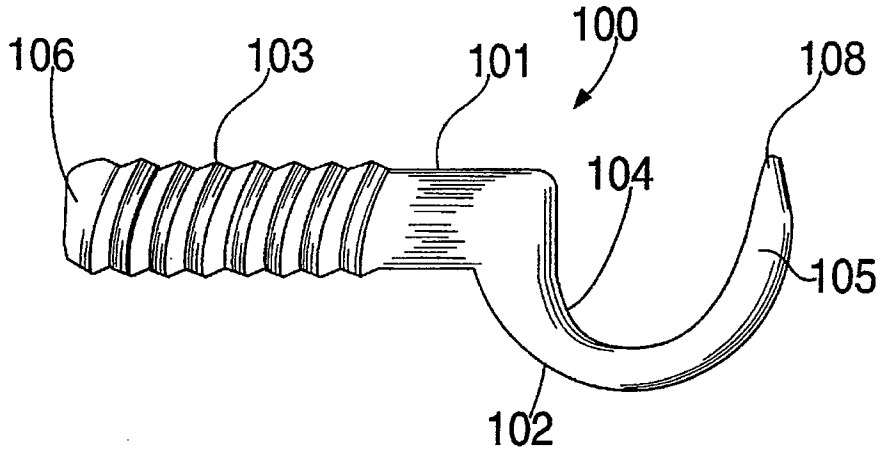


FIG. 1

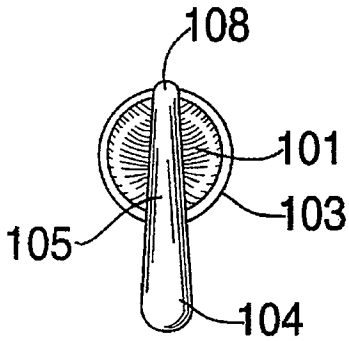


FIG. 2

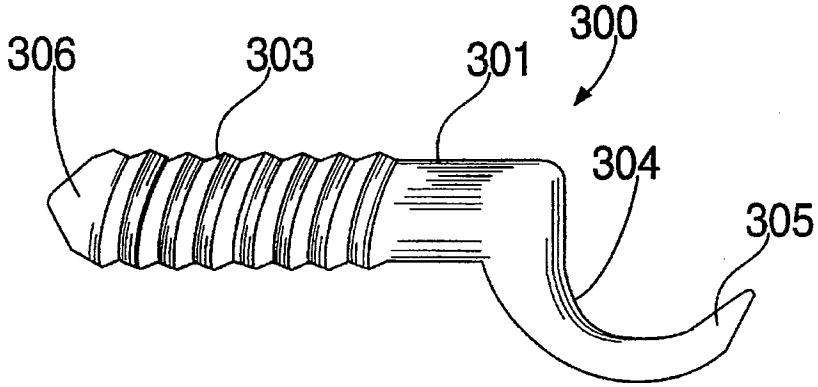


FIG. 5

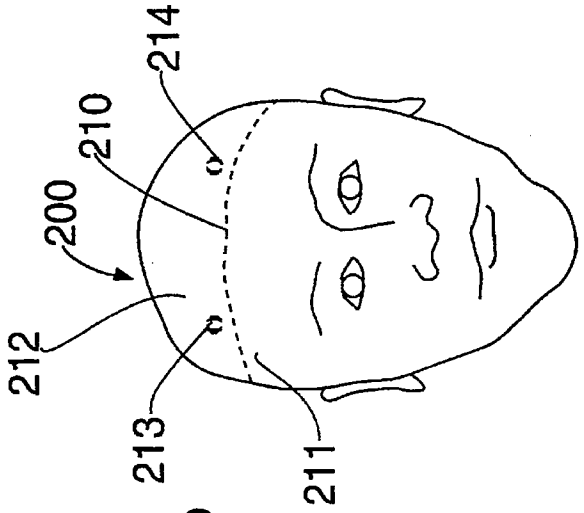


FIG. 4

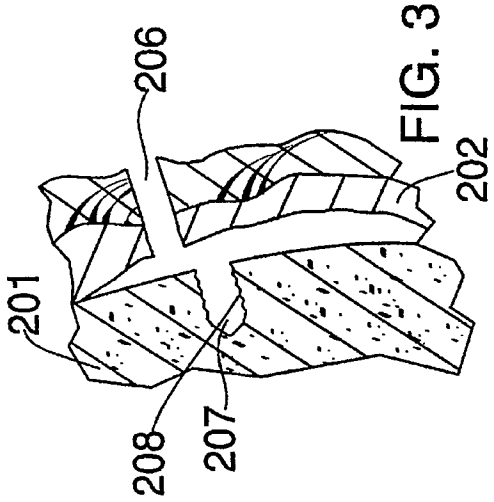


FIG. 3b

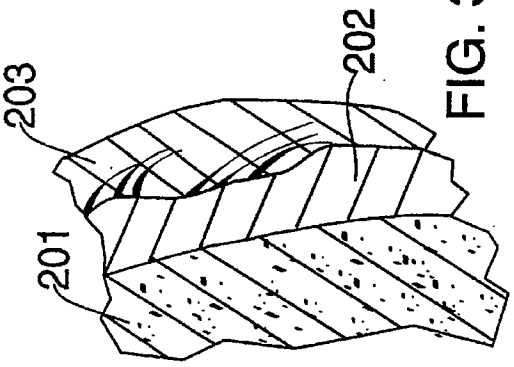


FIG. 3d

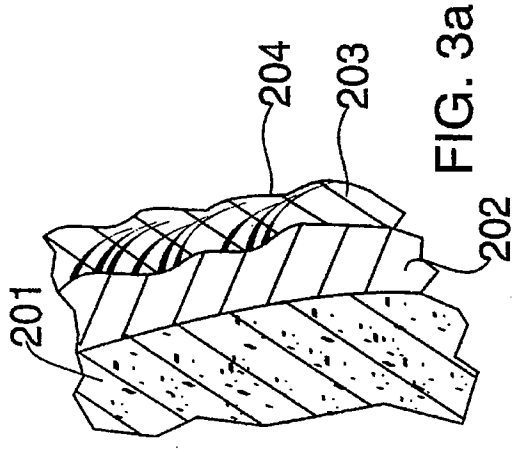


FIG. 3a

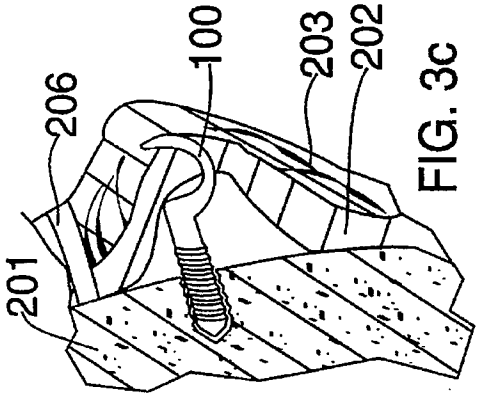


FIG. 3c

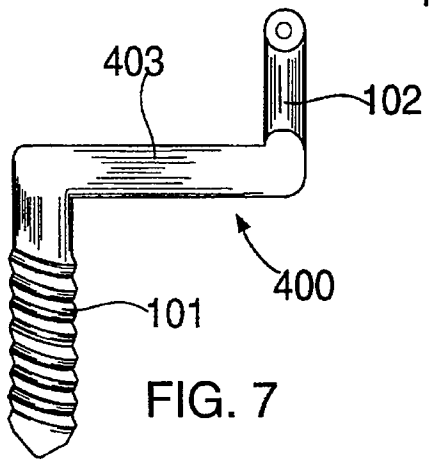


FIG. 7

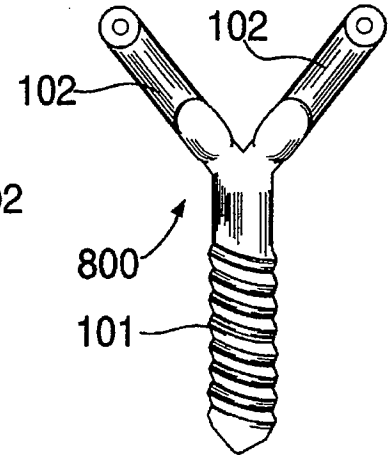


FIG. 6

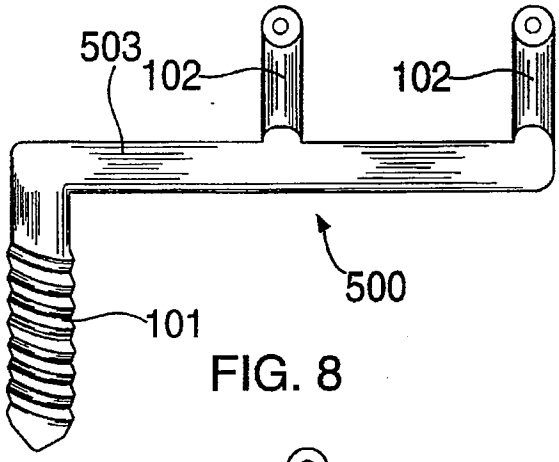


FIG. 8

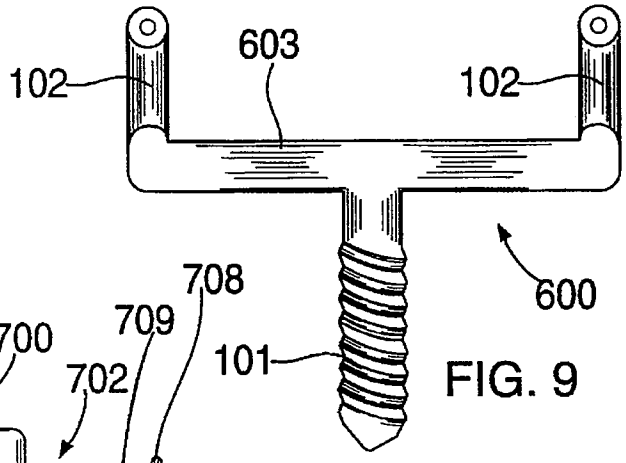


FIG. 9

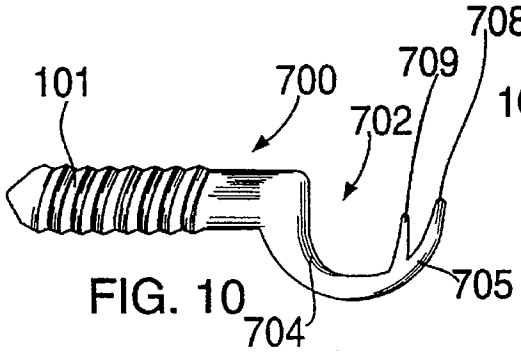


FIG. 10

RESORBABLE SURGICAL APPLIANCES AND ENDOSCOPIC SOFT TISSUE SUSPENSION PROCEDURE

BACKGROUND OF THE INVENTION

The invention is generally directed to the use of resorbable suspension devices in connection with plastic surgery and related surgical procedures and in particular to a new resorbable appliance and the use of a resorbable appliance for use in connection with endoscopic brow lift surgery and similar procedures.

In the past, various approaches have been used to shift and hold soft tissue in place during the course of plastic surgery modification of a patient's anatomy. A brow lift procedure is used to eliminate the generally horizontal lines on a patient's forehead at rest by elevating the top of the patient's brow from the skull and suspending the brow in a superior position for a sufficient period of time so that the soft tissue of the scalp and connective tissue knits in place, leaving the patient with an unlined brow. In the past, invasive surgery using standard surgical cutting tools and open surgical sites using a scalpel have resulted in large entry wounds which tend to create large scars which must be hidden, where possible, under the patient's hairline. However, in many cases, the patient's hairline is inadequate as a means for camouflaging the surgical incision and as a result, these operations were generally not favored due to the complications as well as the large scars which would result.

As the state of the art of surgery improved, it became possible to conduct the brow lift surgery with the use of an endoscope which allows the physician to make a small incision and then extend the tools to be utilized through the small slit and view the work area with the endoscope and complete the surgery without the need for a large surgical incision. The endoscope is similar to the arthroscope utilized in connection with surgery conducted on the knees, shoulders and elbows. In the traditional surgery the soft tissue of the scalp above the brow is held in place by an outside support. Recently, surgical pins or posts have been put in place in the skull to anchor the soft tissue in place. After a period of time following the completion of the healing process, during which the soft tissue is firmly bonded into its new location, the surgeon must reenter the site, remove the pin or post and then reclose the incision. This procedure increases the risk of infection as a substantial risk of infection exists each time an incision is made. In addition, the volume occupied by the removed pin creates an internal space susceptible to collection of fluids and other undesired results. Furthermore, the patient must return and must again suffer the pain or at least discomfort of further incision including the risk of anesthesia whether local or general as well as the need to have further bandages. In some cases it is possible to permanently leave the metal posts or pins in the wearer's skull. However, for purely cosmetic procedures such as the brow lift, most patients are reluctant to have metal pins or posts inserted into their skull, either to remain forever or to be removed at some later date.

As an improvement to the basic brow lift surgery conducted with traditional surgical techniques, the applicant herein has developed a system for endoscopic brow lifts incorporating a portion of a surgical pin cut to the appropriate lengths. Each of these pins is inserted through incisions made through the scalp in connection with the endoscopic procedure to suspend parts of the patient's scalp.

Finally, after the tissue has healed in place and the edema has gone down, another endoscopic procedure is required to remove the pins. Again, the risks inherent in reentry are present as well as the discomfort, inconvenience and additional cost to the patient for a second, albeit smaller, surgical procedure.

Accordingly, there is the need for an improved surgical appliance for supporting soft tissue in a specified fixed location in which the surgeon would only need to once invasively enter the patient's body. It is desired to have the material utilized to suspend the soft tissue or scalp be formed of a material which has the appropriate structural requirements necessary to retain the soft tissue under tension in place and that those characteristics be maintained for a sufficient time to allow complete healing. Thereafter the appliance should be absorbed by the body naturally over a period of time so that no further surgical procedure is necessary.

SUMMARY OF THE INVENTION

The invention is generally directed to a surgical appliance for use in supporting soft tissue in a superior position in the body. The surgical appliance includes a coupling member adapted to connect the surgical appliance to a bone or hard tissue. A gripping member or members secured to the coupling member selectively grips soft tissue and retains the soft tissue in a superior position. A resorbable mixture is used to form the coupling and gripping members so that the coupling member maintains a specified percentage of a connection strength with the bone or hard tissue for a period of time at least equal to a healing period. The gripping member grips the soft tissue so as to retain the soft tissue in a superior position for a period of time at least equal to the healing period. Thereafter, the surgical appliance is substantially resorbed by the body over a period of time greater than the healing period. As a result, in a single procedure the surgical appliance may be inserted, enable movement of the soft tissue to a superior position and retain the soft tissue's superior position for a healing period without the need for a second procedure to remove the surgical appliance or the permanent presence of the surgical appliance in the body.

Another object of the invention is a surgical procedure for supporting soft tissue in a superior position in the body without the need for a second procedure to remove a surgical appliance or the permanent presence of the surgical appliance in the body. An incision is made through the skin and soft tissue to a supporting structure, a hole is drilled and tapped in the supporting structure, a resorbable surgical appliance having a threaded end and a gripping end is screwed into the tapped hole in the support structure. Next, the soft tissue is biased toward the superior position and the soft tissue is draped in place by the gripping member. The incision is closed and the surgical appliance holds the soft tissue in the superior position for at least a period of time equal to a healing period. Thereafter, over a period of time the surgical appliance is absorbed by the body so that the superior position of the soft tissue is permanently retained without the need for further procedures or the continuing presence of a surgical appliance.

Another object of the invention is to provide an improved resorbable surgical appliance for endoscopic brow lift surgeries.

Yet a further object of the invention is to provide improved resorbable surgical appliances for use, in pairs in connection with endoscopic brow lift surgery whereby

minute incisions in a single procedure can cure brow furrows without the need for further procedures to remove surgical appliances, external support or the permanent presence of surgical appliances in the body.

Still another object of the invention is to provide an improved resorbable surgical appliance for use in plastic surgery for anchoring the brow in a new, more superior position as in an endoscopic brow lift.

Yet a further object of the invention is to provide improved resorbable surgical appliance for use in anchoring the face (as in a face lift) in a more youthful position.

Still another object of the invention is to provide an improved surgical appliance for suspending any soft tissue such as skin, muscle and/or fascia, from a bony prominence as in reconstructive surgery.

Still yet another object of the invention is to provide an improved resorbable surgical appliance for use in scalp surgery (as in scalp reduction for hair loss) to anchor the scalp and minimize scars by diverting tension from wound edges and giving a better scar.

Yet a further object of the invention is to provide an improved surgical appliance for supporting soft tissue so as to minimize scar formation by diverting tension from wound edges and giving a less substantial scar formation and a cleaner healing of the skin tissue.

Yet still a further object of the invention is to provide an improved absorbable surgical appliance for use in a body form maintaining soft tissue in a superior position under tension for a sufficient period time for the soft tissue to retain its superior position without support and thereafter for the surgical appliance to be absorbed by the body.

Still yet another object of the invention is to provide an improved operating procedure for endoscopically lifting a patient's brow utilizing an absorbable surgical appliance which screws into adjacent portions of the skull and, after the brow has rehealed in a superior position is absorbed completely by the body.

Still other objects and advantages of the invention will in part be obvious and will in part be apparent from the specification.

The invention accordingly comprises the features of construction, combinations of elements, arrangements of parts, series of steps and identification of procedures which will be exemplified in the constructions and procedures hereinafter set forth and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference is had to the following description taken in connection with the accompanying drawings, in which:

FIG. **1** is an enlarged perspective view of a resorbable surgical appliance constructed and arranged in accordance with a preferred embodiment of the dimension;

FIG. **2** is a right side view of the surgical appliance of FIG. **1**;

FIG. **3A** is an enlarged partial cross-sectional view taken along a vertical line showing the brow and skull region to receive the surgical appliance prior to the procedure;

FIG. **3B** is a cross-section similar to the cross-section of FIG. **3A** following creation of an endoscoping work incision, the drilling of a small hole in the skull and the tapping of the drilled hole;

FIG. **3C** is a cross-sectional view similar to the cross-sectional view of FIG. **3A** showing the soft tissue of the scalp and brow separated from the skull and the soft tissue of the brow and scalp is pulled up and secured on the hook end of the surgical appliance;

FIG. **3D** is a cross-sectional view similar to FIG. **3A** after the surgical appliance has been absorbed by the body;

FIG. **4** is a front elevational view of a patient's head showing the outward manifestation of the surgical procedure following its completion;

FIG. **5** is a perspective view of a surgical appliance constructed in accordance with another embodiment of the invention;

FIG. **6** is a front elevational view of a surgical appliance constructed in accordance with another preferred embodiment of the invention;

FIG. **7** is a front elevational view of a surgical appliance constructed in accordance with another preferred embodiment of the invention;

FIG. **8** is a front elevational view of a surgical appliance constructed in accordance with a further preferred embodiment of the invention;

FIG. **9** is a front elevational view of a surgical appliance constructed in accordance with another preferred embodiment of the invention; and

FIG. **10** is a perspective view of an alternate embodiment of the surgical appliance constructed in accordance with another preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is made to FIGS. **1** and **2** wherein a resorbable surgical appliance, generally indicated as **100** constructed in accordance with preferred embodiment of the invention is depicted. Surgical appliance **100** includes a connective portion **101** and a gripping portion **102**. Connective portion **101** has a threading **103** about its circumference. Connective section **101** has a generally round cross-section from end **106** to rounded hook portion **107**. End **106** is shown as terminating in a frustumated cone and not a sharp point. However, as shown in other embodiments below, end **106** can also be formed with a tapered end coming to a point. Gripping end **102** has curved portion **107** which is directly adjacent connected portion **101** and terminates in hook point portion **105**. Hook point portion **105** is shown as terminating in a generally pointed end, generally aligned with the base of connected portion **101** at the point at which it joins rounded portion **107**. In other preferred embodiments, as shown below, hook portion **105** may either extend further so that it extends beyond the imaginary continuation of connective portion **101** or may be smaller and terminate within the imaginary extension of cylindrical portion **101**. As best seen in FIG. **2**, the tip **108** of hook portion **105** is in line with a cylindrical connected portion **101**. Likewise, the curved section **107** extends above the top of cylindrical connective portion **101**. These connections can be modified based upon the specific needs of the surgical procedure involved.

Surgical appliance **100** is formed of a resorbable mixture which is absorbed by the body over a period of time. Generally, the length of time over which the resorbable material deteriorates within the body is controlled so that the surgical appliance retains a required percentage of its holding strength for holding soft tissue for skull tissue in the desired superior position for a sufficient time for the soft

tissue or scalp tissue to reestablish contact with the surrounding harder tissues or bones and knit naturally so that upon degradation and absorption of the surgical appliance the soft tissue or scalp tissue will not move from the superior position it has been placed at during the surgical procedure.

In a preferred embodiment, surgical appliance **100** is formed of a blend of polylactic acid and polyglycolic acid in combination adjusted so as to assure that at least 70% of the initial holding power of the surgical appliance is maintained for a healing period and thereafter after an absorption period, the complete surgical appliance has been absorbed.

In a preferred embodiment surgical appliance **100** should maintain at least 50% of its holding power for the healing period, in a more preferred embodiment the initial holding power should be maintained within a range of at least 60%–80% of the holding power and an even more preferred embodiment at least 70% of the initial holding power is maintained for the holding period.

In a preferred embodiment the holding period is at least three weeks, preferably four to eight weeks and even more preferably at least six weeks. Finally, the material should fully absorb preferably within one year, more preferably within six to ten months and even more preferably within about nine months. These optimum levels are based upon use of the surgical appliance in connection with endoscopic brow lift surgery. Different optimum periods and percentages of holding power will be necessary depending upon the nature of the surgery contemplated.

By varying the composition of the materials the absorption of the material utilized can be affected so as to either enhance or delay absorption.

Reference is next made to FIGS. **3A–3D** and **4** in which a procedure for endoscoping brow lift surgery is generally depicted. The drawings are of a basic, sketch-like variety and are not intended to accurately reproduce the underlying structures, blood vessels, nerve fibers and tissue structure found at or about the brow and skull of an actual patient.

FIG. **3A** shows the brow region of the patient in side cross-section, generally showing a furrowed brow prior to an endoscopic brow lift surgical procedure. Generally, the figure shows a human head generally indicated as **200** including skull **201**, soft tissue **202**, scalp **203** and furrows **204**.

In FIG. **3B**, a small incision **206** is made above the hairline **210** (FIG. **4**) and the endoscope (not shown) is inserted. The endoscope is a well known tool for viewing and controlling delicate surgery performed through a small slit, rather than a large incision in which the field of activities is exposed. The soft tissue **202** and scalp **203** are elevated through the visual control available as a result of the endoscope's use. This elevation is also conventionally performed. In the embodiment of FIG. **3B** a small hole **207** has been drilled into skull **206** and hole **207** has had threading **208** added to it by a tapping device which is conventionally available.

Reference is next made to FIG. **3C** wherein surgical appliance **100** is introduced into tapped hole **207**. Leading end **106** is placed in the opening of the hole and appliance **100** is screwed in until the appropriate depth of connection and appropriate extension of gripping end **102** is achieved.

Also in FIG. **3C** the scalp **203** and soft tissue, **202** are stretched upward so as to remove the furrows **204** in scalp **202**. The inside of soft tissue **202** and scalp **203** are grabbed and pierced by the hook **105** and hook end **108** so that there is a snug and secure connection and tensile pressure holding the soft tissue **202** and scalp **203** taut and smooth over the visible portion of the patient's brow. The tip **108** does not protrude from the outside of scalp layer **203**.

Finally, FIG.**3D** shows the final stage of the procedure following the period during which the scalp and other soft tissue has been held in the new, superior position up against scalp **201** for a sufficient healing period, generally for at least three weeks preferably four to six weeks and even more preferably for at least six weeks. Thereafter, as the resorbative material of surgical appliance **100** is absorbed after an absorption period which is preferably under a year, even more preferable, six to twelve months and even more preferably by about nine months, surgical appliance **100** has been completely absorbed by the patient's body, the bone mass drilled out in hole **207** has grown back and no evidence of the procedure remains other than the smooth outer brow surface desired. Scalp **203** and soft tissue **202** heals and knits firmly with the bony surface of skull **201** along the brow in the new, superior position enabled and maintained by surgical appliance **100** during its period of residence within the brow region.

In a preferred embodiment the entire length of surgical appliance **100** is 6 millimeters, the length of the connective or threaded portion is 2 millimeters and the length of the supporting portion is 4 millimeters. Gripping portion **102** has a height, perpendicular to the horizontal extent of threaded portion **101** of 4 millimeters. The diameter of threaded portion **101** is 2 millimeters. As noted above, these dimensions may vary depending upon the nature and extent of the surgery involved.

Reference is next made to FIG.**4** wherein a frontal view of a patient after undergoing the endoscopic brow lift surgery in accordance with the preferred embodiment described above including use of resorbtive surgical appliance **100** is depicted. As seen in FIG.**4** the head **200** includes the hairline **210** separating the exposed brow portion **211** from hair covered portion **212**. In hair covered portion **212**, two small protrusions **213**, **214** are present which signify the locations at which two surgical appliances **100** are seated above the hairline **210** providing a smooth brow surface **211**.

Over time the bumps or protrusions **213** and **214**, which are caused by the outward extension of surgical appliances **100**, recede as surgical appliance **100** is absorbed by the body. After the surgical appliances **100** are fully absorbed, the bumps will completely disappear and leave no further evidence of their existence. The operation can even be performed on individuals with limited or no hair in view of the tiny incision initially made and the only minor visibility of the bumps **213**, **214**.

Reference is next made to FIG.**5** wherein a surgical appliance generally indicated as **300** constructed in accordance with another preferred embodiment of the invention is depicted, like reference numerals depicting like elements. Surgical appliance **300** includes a connective region **101** by having screw portion **103** and end portion **306** coming to a tapered point. This is contrasted with surgical appliance **100** in which tip **106** ends in a flattened surface. Also, rounded portion **302** includes a shortened rounded section **304** and hook portion **305**. Rather than extending with a full hook back up to the top surface of surgical appliance **300** as is done with hook point **108** of hook **105** in surgical appliance **100** of FIG. **1**, less curvature is present. This hook structure may be similarly utilized with other appliance forms as shown in FIGS. **6–10**.

Reference is next made to FIG. **6** wherein a surgical appliance, generally indicated as **800**, constructed in accordance with another preferred embodiment of the invention is

depicted. Surgical appliance **800** includes a screw portion **101** and two hook portions **102** at right angles to each other. Depending upon the needs of the surgical procedure greater or lesser interior angles can be established. Also, the hook portions **102** can be placed on a single screw portion **101** for even greater stability and strength.

Reference is next made to FIG. **7** wherein a surgical appliance generally indicated as **400** constructed in accordance with another preferred embodiment of the invention is depicted. Surgical appliance **400** includes a screw portion **101** and a hook portion **102** connected by a lateral displacement bar section **403** which allows the hook **102** to be displaced from the position at which the screw hole is placed. Bar **403** may be made of varying lengths depending upon the displacement intended or required under the circumstances of the procedure. Often, no suitable bone or hard tissue is present at the point that the soft tissue must be moved to a superior position and the surgical appliance **400** provides the flexibility to adapt the use of a resorbable surgical appliance to such procedure.

Reference is next made to FIG. **8** wherein a resorbable surgical appliance generally indicated as **500** constructed in accordance with another preferred embodiment of the invention is depicted, like reference numerals representing like elements. Surgical appliance **500** includes a screw or connector end **101** and two hook gripping portions **102** spaced along a connective bar **503** on one side of screw portion **101**. Again, depending upon the circumstances and nature of the procedure and the availability of appropriate bone structures to support the surgical appliance, two or more hook portions **102** may be spaced along the length of bar **503**.

Reference is next made to FIG. **9** wherein a surgical appliance generally indicated as **600** constructed in accordance with another preferred embodiment of the invention is depicted, like reference numerals representing like elements. Surgical appliance **600** includes a screw portion **101** and two hook portions **102** spaced apart along horizontal support bar **603**. Surgical appliance **600** allows for two portions of soft tissue to be suspended from a single surgical appliance. The hook portions **102** may also be made smaller so that less displacement away from the bone surface is provided. In addition to the structure shown, two or more hook portions **102** may be added on each side of screw portion **101** as required in connection with each procedure. It is not necessary that the hooks be either symmetrically or regularly placed. Rather, the hooks can be placed where required for each specified surgical procedure.

Reference is next made to FIG. **10** wherein a surgical appliance generally indicated as **700** constructed in accordance with another embodiment of the invention is depicted, like reference numerals representing like elements. Surgical appliance **700** includes a screw portion **101** and a hook portion **702** having a rounded portion **704** and a hook portion **705**. Hook portion **705** includes a primary point **708** and an additional barb **709** to provide additional gripping power. Various fish hook or other types of barbs may be utilized to increase the holding power of the surgical appliance as necessary.

The surgical appliance **100** and the variations thereof identified as surgical appliances **300, 400, 500, 600** and **700** may be modified and constructed of various sizes and shapes as required by the parameters and needs of varying types of surgical, procedures. In connection with the endoscopic brow lift surgery, in a preferred embodiment the entire surgical appliance **100** has a length of about 10 millimeters of which **6** millimeters represents the screw portion **101** and 4 millimeters represents the length of the hook portion **102**. Hook portion **102** also has a height from the tip **108** of the hook point **105** to the base of rounded portion **104** of about 4 millimeters. Screw portion **101** also has a diameter of about 2 millimeters. Smaller or larger dimensions may be made depending upon the varying needs, strengths and positions in which surgical appliances **100** and related variations thereof **300, 400, 500, 600** and **700** are utilized. Each of the surgical appliances disclosed and described may also be utilized in varying ways in varying procedures to provide an improved method for retaining soft tissue, skin and scalp at superior positions in connection with cosmetic, plastic and reconstructive surgery. In addition, particularly in connection with operations which traditionally leave substantial and large scars, the surgical appliances disclosed herein may be used to relieve and reduce tension at the major incision areas so as to aid in more effective healing of the incision with reduced scar tissue formation.

Currently, the endoscopic brow lift surgery is disfavored as a cosmetic surgery in view of the current procedure's failure to provide required cosmetic reparation without either substantial risk of collateral injury related to infection or the need for further surgical procedures to remove surgical appliances after the healing period has been completed. This of course makes a patient susceptible to further risk of infection or anesthetic related problems. Accordingly, an improved surgical appliance which is resorbable and provides improved results in connection with endoscopic brow lift surgery and other surgical procedures is provided.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above construction without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It will also be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

What is claimed is:

1. A surgical appliance for use in supporting soft tissue in a position superior to its natural state in a body, the surgical compliance comprising:

coupling means adapted to connect the surgical appliance to a bone or hard tissue;

gripping means secured to the coupling means for selectively gripping soft tissue and retaining the soft tissue in the superior position, wherein the gripping means includes two hooking members;

resorbable means for forming the coupling and gripping means so that the coupling means maintains a required connection strength with the bone or hard tissue for a period of time at least equal to a healing period, the resorbable means including a resorbable material, the gripping means grips the soft tissue so as to retain the soft tissue in the superior position for a period of time at least equal to the healing period, and for causing the surgical appliance to be substantially resorbed by the body after the healing period;

whereby in a single procedure the surgical appliance may be inserted and enable movement of the soft tissue to a superior position and retention of the soft tissue in said superior position for a healing period, without the need

for a second procedure to remove the surgical appliance or the permanent presence of the surgical appliance in the body.

2. The surgical appliance of claim 1 wherein the two hooking members are angled apart by 90°.

3. The surgical appliance of claim 1 further comprising extender means for connecting and displacing the coupling means and the gripping means, the extender means being formed from the resorbable means.

4. A surgical appliance for use in supporting soft tissue in a position superior to its natural state in a body, the surgical appliance comprising:

coupling means adapted to connect the surgical appliance to a bone or hard tissue;

gripping means secured to the coupling means for selectively gripping soft tissue and retaining the soft tissue in the superior position, wherein the gripping means includes at least two separate hook members secured to the extender means;

resorbable means for forming the coupling and gripping means so that the coupling means maintains a required connection strength with the bone or hard tissue for a period of time at least equal to a healing period, the resorbable means including a resorbable material, the gripping means grips the soft tissue so as to retain the soft tissue in the superior position for a period of time at least equal to the healing period, and for causing the surgical appliance to be substantially resorbed by the body after the healing period;

extender means for connecting and displacing the coupling means and gripping means, the extender means being formed from the resorbable means;

whereby in a single procedure the surgical appliance may be inserted and enable movement of the soft tissue to a superior position and retention of the soft tissue in said superior position for a healing period, without the need for a second procedure to remove the surgical appliance or the permanent presence of the surgical appliance in the body.

5. The surgical appliance of claim 4 wherein the extendor means extends perpendicular to the coupling means and hook members are found on both sides of the coupling means.

6. The surgical appliance of claim 4 wherein the gripping means includes a hook having a primary point and an additional barb.

7. A surgical procedure for supporting soft tissue in an improved position in a body incorporating a resorbable surgical appliance, the procedure comprising:

making a small entry slit proximate to soft tissue to be moved;

inserting an endoscope into the small opening for viewing surgical activity under skin;

separating the soft tissue and skin from a bone;

drilling a hole in a bone tissue proximate the soft tissue to be moved;

tapping threads into the hole;

screwing a resorbable surgical appliance, having a threaded end and a hook end, into the threaded hole;

moving the soft tissue to a desired superior position and draping the soft tissue over the hook portion of the surgical appliance so that the hook end pierces the soft tissue and retains it under tension in the desired improved position;

closing the entry slit;

whereby the soft tissue is maintained in the improved position for at least a healing period by the resorbable surgical appliance which thereafter is resorbed by the patient's body with the bone regrowing to fill the tapped hole following the resorption of the surgical appliance, without the need for further surgical procedure.

8. The procedure of claim 7 further including drilling and tapping a second hole and inserting a second surgical appliance after insertion of the first surgical appliance and draping the soft tissue on both surgical appliances.

9. The procedure of claim 7 wherein the soft tissue and skin being moved is a portion of a brow.

* * * * *

US005950633A

United States Patent [19]

Lynch et al.

[11] Patent Number: 5,950,633

[45] Date of Patent: Sep. 14, 1999

[54] **MICROSURGICAL TECHNIQUE FOR COSMETIC SURGERY**

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[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **08/942,926**

[22] Filed: **Oct. 2, 1997**

[51] **Int. Cl.**[6] **A61B 19/00**

[52] **U.S. Cl.** **128/898**; 623/16; 606/53; 606/60; 606/73; 606/139

[58] **Field of Search** 128/897, 898; 606/213, 53, 60, 72, 73, 104, 139; 623/11, 16, 66

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Primary Examiner—Mickey Yu

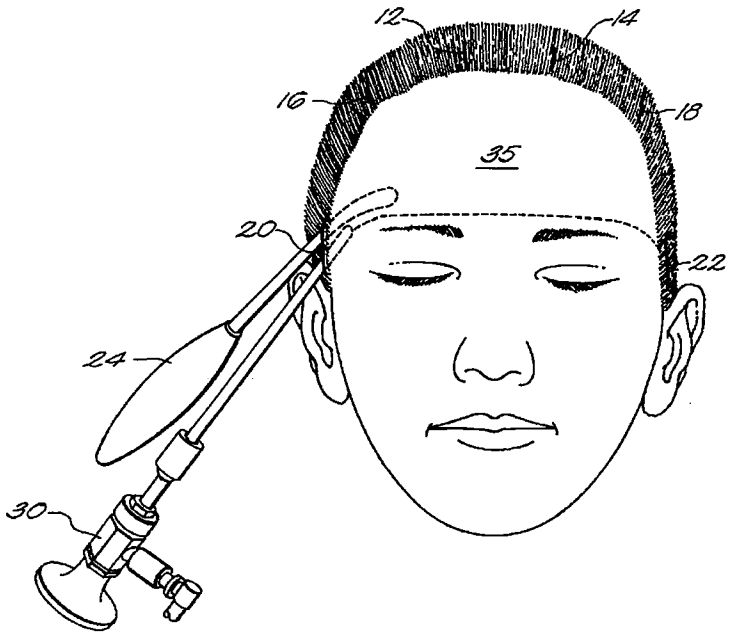
Assistant Examiner—Dinh X. Nguyen

Attorney, Agent, or Firm—Nutter, McClennen & Fish, LLP

[57] **ABSTRACT**

A procedure for supporting the soft tissue of a patient's scalp in a superior position using a microanchor includes forming a plurality of incisions proximate to the soft tissue to be moved, inserting an endoscope through at least of one of the incisions and undermining the soft tissue to be moved while at least a portion of the undermining process is viewed through the endoscope. At least one microanchor having a generally cylindrical body including a first bone contacting end, a second trailing end and bone fixation means formed on at least a portion of an outer surface of the microanchor between the first and second ends is provided. Each of the one or more microanchors has a length of less than about 4.0 mm and has a predetermined length of suture thread attached thereto. At least one pilot hole is formed in the patient's cranium through the incisions made therein. The one or more microanchors are inserted into the one or more pilot holes, the soft tissue is moved to the desired superior position and the soft tissue is sutured into that position using the suture thread attached to the microanchor.

16 Claims, 6 Drawing Sheets



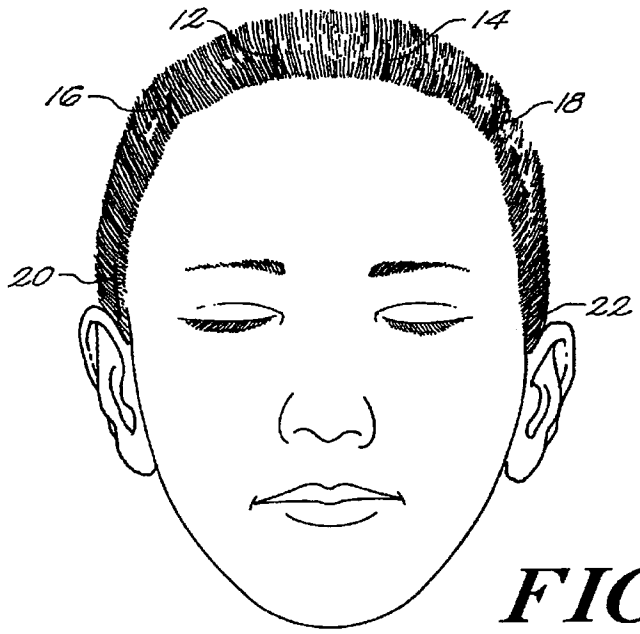


FIG. 1

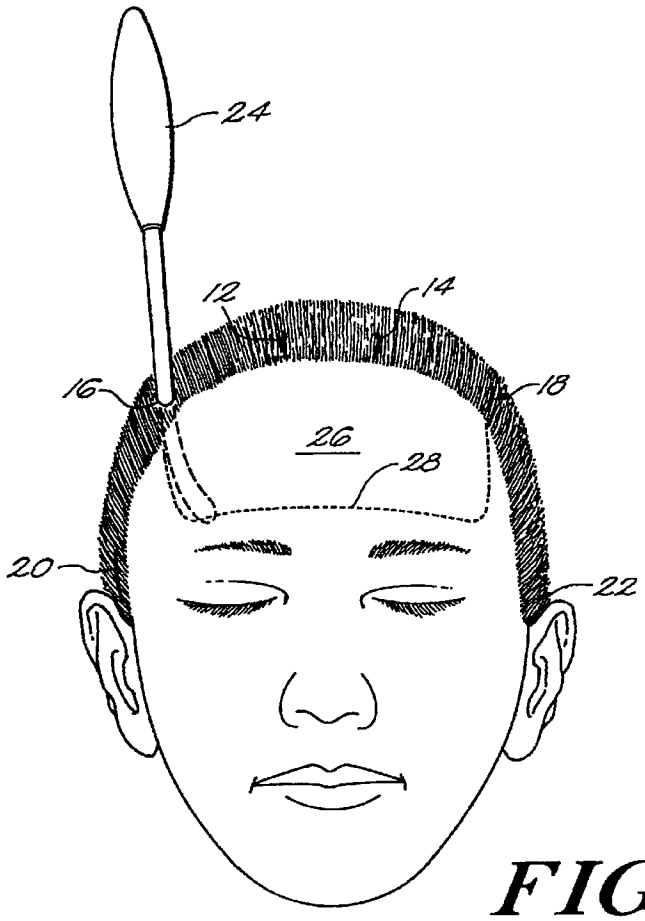


FIG. 2

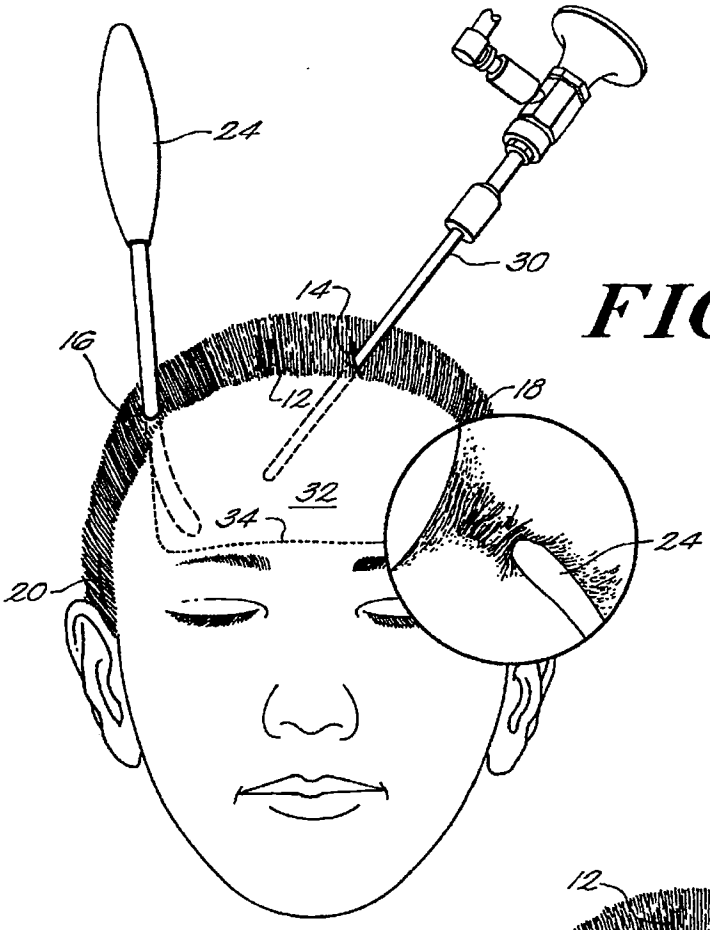


FIG. 3

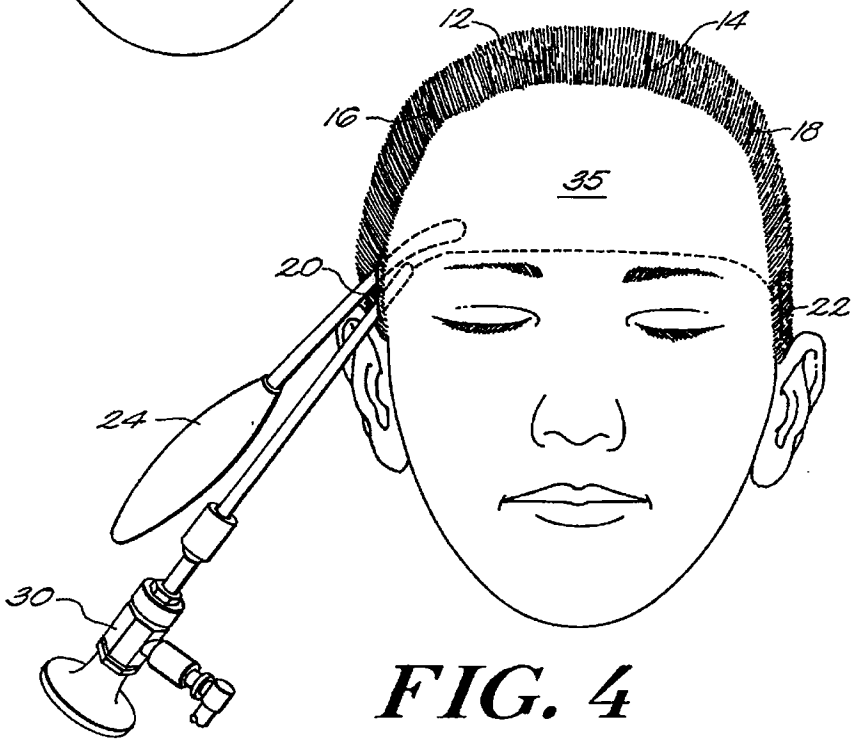


FIG. 4

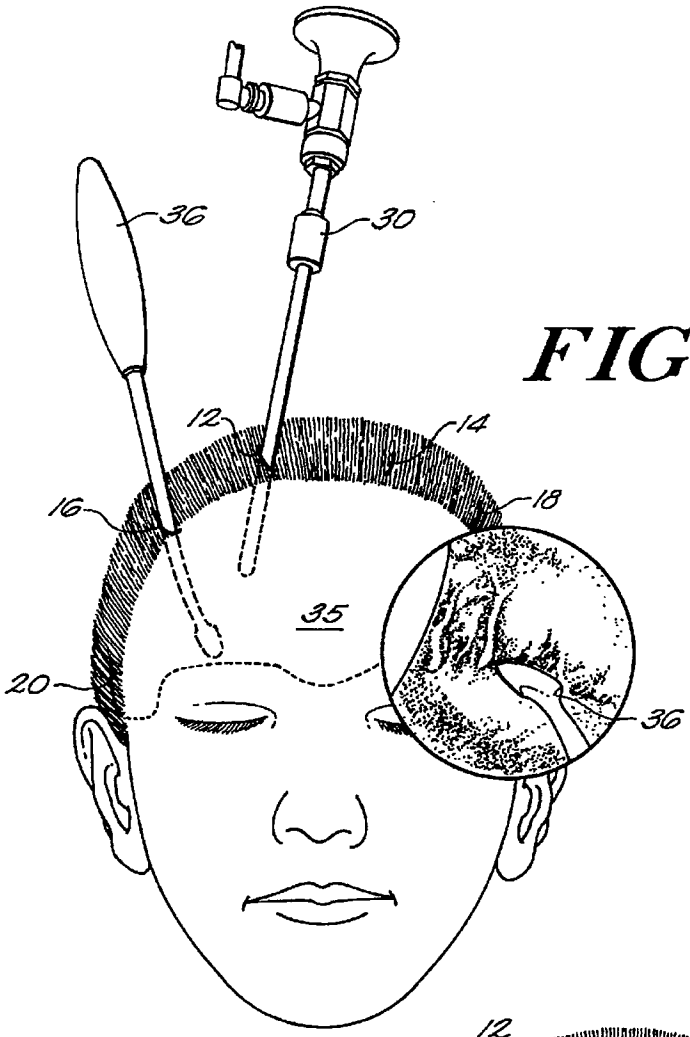


FIG. 5

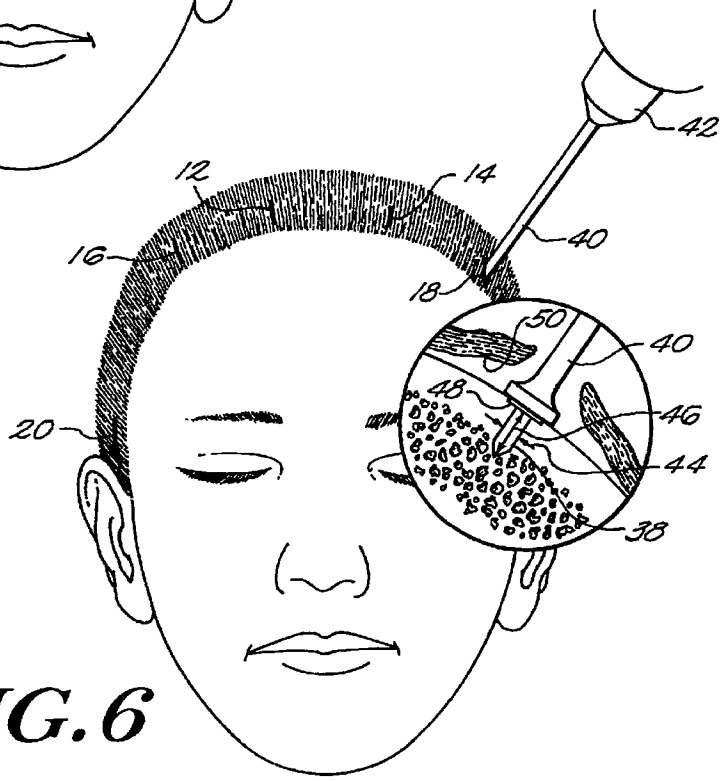


FIG. 6

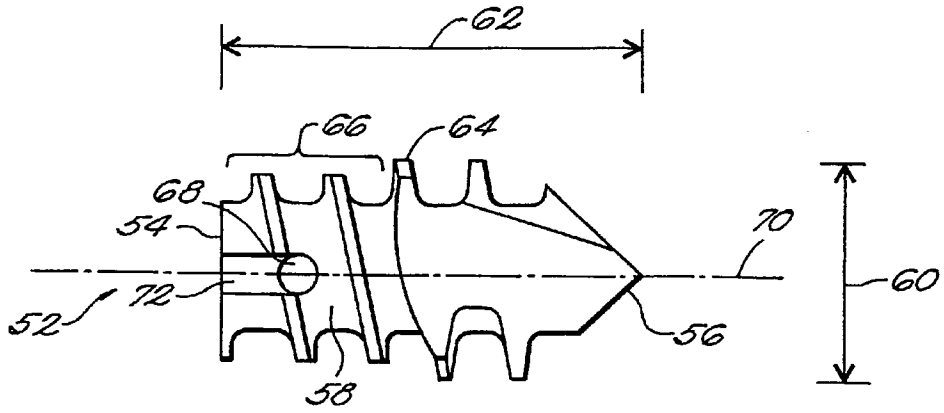


FIG. 7

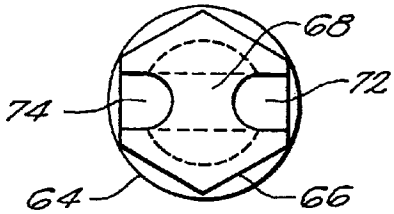


FIG. 8

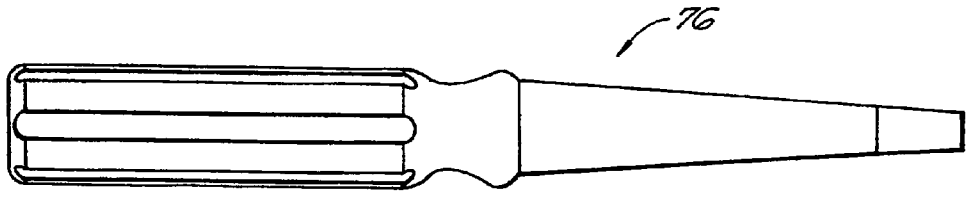


FIG. 9

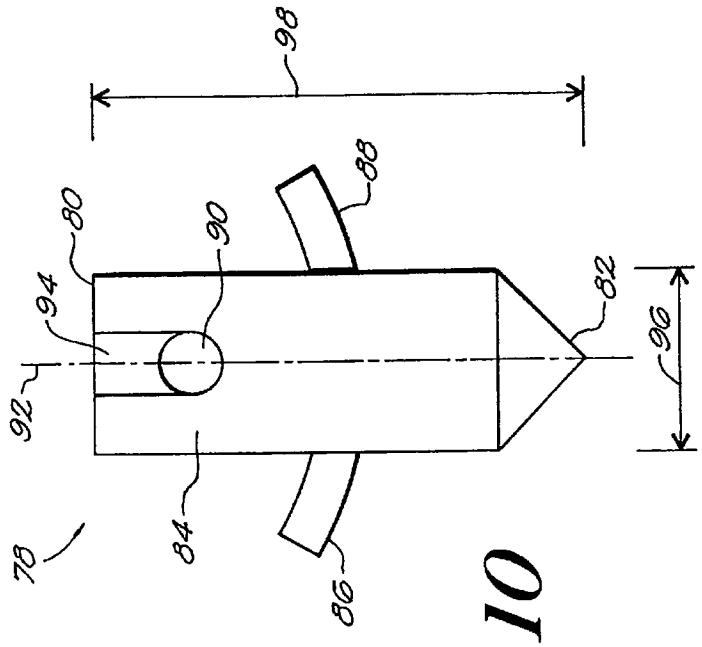


FIG. 10

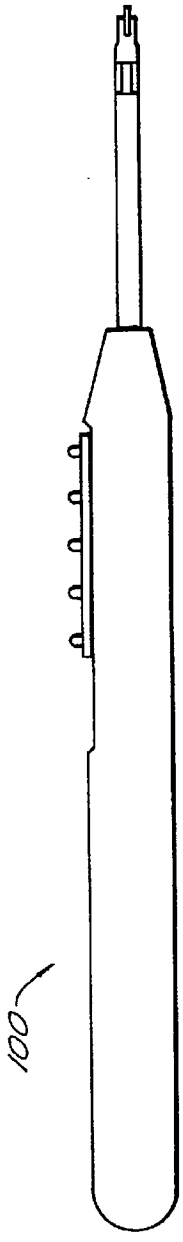


FIG. 11

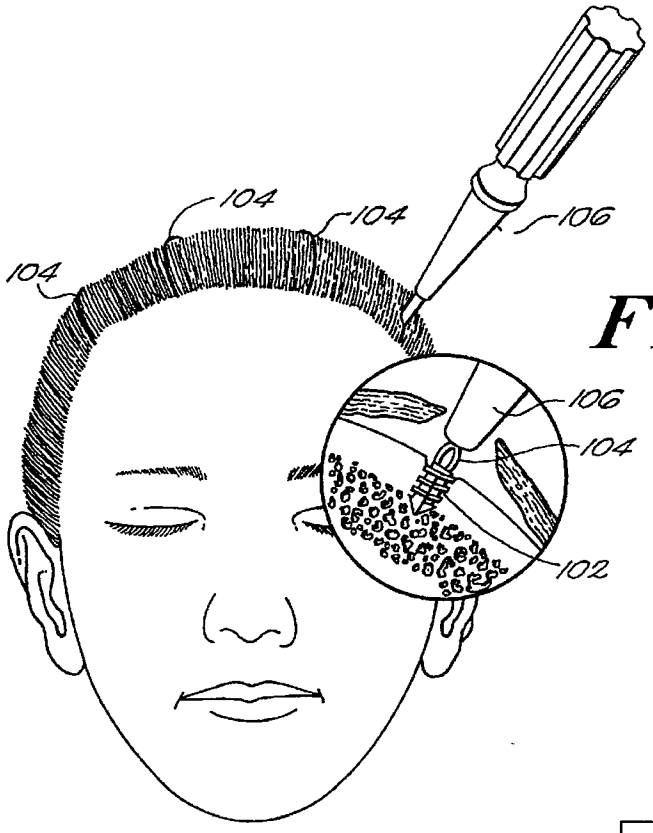


FIG. 12

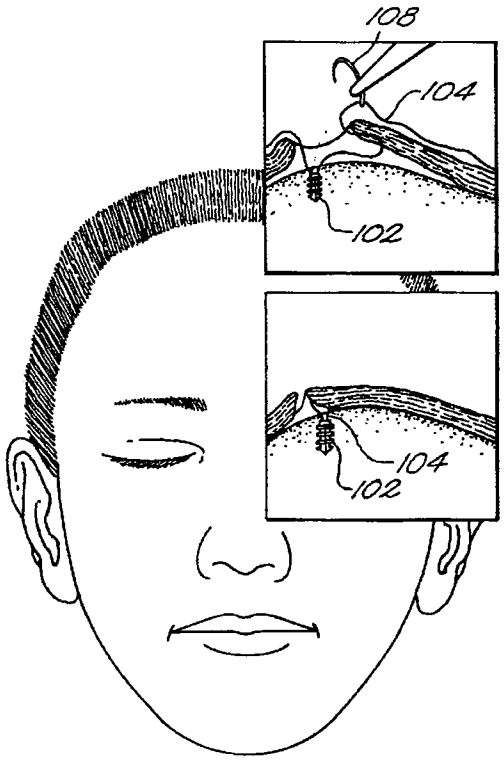


FIG. 13

MICROSURGICAL TECHNIQUE FOR COSMETIC SURGERY

CROSS-REFERENCE TO RELATED APPLICATION

Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable.

FIELD OF THE INVENTION

The present invention relates to a technique for performing plastic or cosmetic surgery using microanchors.

BACKGROUND OF THE INVENTION

The brow lift is a basic procedure for rejuvenating the upper portion of a patient's face. The brow lift procedure may be used to elevate the eye brows, remove or lessen forehead wrinkles, reduce frown lines, smooth the nasion and elevate the nasal tip. These results are generally achieved by elevating the top of the patient's brow from the skull and suspending the brow in a superior position for a sufficient period of time so that the soft and connective tissues of the patient's scalp knit in place, leaving the patient with the desired effects.

In the past, surgeons performed invasive surgery using standard surgical tools at open surgical sites, typically performing a bicoronal incision with subgaleal dissection, to complete a brow lift procedure. These techniques were very limited in their application and resulted in significant scarring to the patient.

More recently, surgeons have begun to use endoscopic techniques to perform brow lift procedures. Endoscopic procedures allow the surgeon to make a small incision or incisions, extend surgical tools through the small incisions and perform the procedure while viewing the surgical site with an endoscope. In this manner, the brow lift procedure is performed without the need for large surgical incisions that are required in open surgical techniques.

Once the surgeon has moved the brow to a superior position, the soft tissue must be suspended in that position for a sufficient time to allow healing to occur. External means, such as screws and staples, have been used to suspend the soft tissue in place. These devices may leave the patient susceptible to infections, require a great deal of bandaging and leave extensive scars. More recently, internal means, such as surgical pins or posts, have been applied. These devices work for their intended purposes, but they require the surgeon to reopen the skin to remove them and they can create an internal space which is susceptible to undesirable effects such as fluid collection.

Additionally, tissue fixation methods that do not a require reopening of the patient's skin to remove fixation devices have been attempted, including bone tunneling and deployment of resorbable fixation devices. Bone tunneling involves drilling two interconnecting holes into the patient's cranium and leaving a "bridge" between the holes. A suture thread may then be routed though this tunnel and used to fix the patient's scalp tissue in place. Despite the strength of cranial bone, this method can be difficult to perform without weakening or breaking the bone "bridge" that fixes the suture thread to the cranium. Resorbable fixation devices also have drawbacks, including the inability to adjust the timing of the fixation device's release after implantation in response to individual healing rates and the creation of internal spaces as with surgical pins or posts.

SUMMARY OF THE INVENTION

The present invention provides a procedure for supporting the soft tissue of a patient's scalp in a superior position using a device, such as a microanchor, for anchoring sutures to bone. The procedure includes forming a plurality of incisions proximate to the soft tissue to be moved. An endoscope is then inserted through at least of one of the incisions and the soft tissue to be moved is undermined while at least a portion of the undermining process is viewed through the endoscope.

At least one suture anchor device having a generally cylindrical body including a first bone contacting end, a second trailing end and bone fixation element formed on at least a portion of an outer surface of the suture anchor between the first and second ends is provided. Each of the one or more suture anchor devices has a length of less than about 4.0 mm and has a predetermined length of suture thread attached thereto.

At least one pilot hole is formed in the patient's cranium through the incisions made therein. The one or more suture anchor devices are inserted into the one or more pilot holes, the soft tissue is moved to the desired superior position and the soft tissue is sutured into that position using the suture thread attached to the anchor device.

In one embodiment, the suture anchor device is a threaded microanchor having a length of less than about 4.0 mm and a major diameter of less than about 2.4 mm. Preferably, the threaded microanchor has a length of about 3.5 mm and a major diameter of about 2.0 mm.

In an additional embodiment, the suture anchor device is a non-threaded microanchor having two opposed deformable barbs capable of penetrating bone tissue. Preferably, the non-threaded suture anchor has a body constructed from a metal and barbs formed from a shape-memory material. Generally, the non-threaded suture anchor may have a length of less than about 4.0 mm and a diameter of less than about 1.5 mm. Preferably, the non-threaded suture anchor has a length of about 3.7 mm and a diameter of about 1.3 mm.

The pilot holes may be formed using a drill bit having an effective length of less than about 5 millimeters. The drill bit may also have a scoring means suitable to provide clearance around the pilot hole to allow for a suture anchor insertion tool to insert the microanchor at or below the surface of the cranium.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood by reference to the following detailed description when considered in conjunction with the accompanying drawings, in which:

FIG. **1** is an elevated view of a patient's head indicating the location of incisions;

FIG. **2** is an elevated view of a patient's head showing a periosteal elevator in use undermining a portion of the patient's soft tissue;

FIG. **3** is an elevated view of a patient's head showing a periosteal elevator and an endoscope in use with an insert illustrating a view through the endoscope;

FIG. **4** is an elevated view of a patient's head showing a periosteal elevator and an endoscope in use through a temporal incision;

FIG. **5** is an elevated view of a patient's head showing a periosteal elevator and an endoscope in use with an insert illustrating a view through the endoscope;

FIG. **6** is an elevated view of a patient's head showing a drill and drill bit being applied through an incision with a cross-sectional view in insert;

FIG. **7** is an elevated view of a threaded microanchor;

FIG. **8** is an end view of the threaded microanchor of FIG. **7**;

FIG. **9** is an elevated view of a suture anchor inserter for use with the threaded microanchor of FIG. **7**;

FIG. **10** is an elevated view of a non-threaded microanchor;

FIG. **11** is an elevated view of a suture anchor inserter for use with the threaded microanchor of FIG. **10**;

FIG. **12** is an elevated view of a patient's head showing a microanchor being inserted through an incision with a cross-sectional view in insert; and

FIG. **13** is an elevated view of a patient's head illustrating the suturing of soft tissue in two inserts.

DETAILED DESCRIPTION OF THE INVENTION

The present invention concerns a procedure for supporting the soft tissue of a patient's scalp in a superior position using a suture anchor device. The patient is brought into an operating room where either general or intravenous sedation anesthesia is administered. The patient's face and scalp are cleansed with an antiseptic solution and draped under a sterile technique.

As shown in FIG. **1**, two medial parasagital **12, 14** and two lateral **16, 18** brow incisions approximately 1 cm proximal to the hairline and 1.5 to 2.0 cm in length, are made and carried down to the periosteum. Bilateral temporal scalp incisions **20, 22** are made to allow access to the temporal parietal region. The temporal scalp incisions **20, 22** start approximately 1 cm above the root of the helix of the ear and extend superiorly 3 cm. Alternatively, five scalp incisions may be used instead of six, combining the two medial incisions **12, 14** into one central incision. The lateral scalp incisions **16, 18** may also be angled 30 degrees, providing more lateral eyebrow elevation and altering the eyebrow shape. The scalp incisions are infiltrated with a 1% lidocaine and 1:100,000 epinephrine solution. The remainder of the scalp is infiltrated with a dilute local anesthetic, according to the preference of the surgeon. One of ordinary skill in the art will appreciate that alternative incisions, varying in size and location from those noted above, may be effectively utilized without departing from the scope of the invention.

A periosteal elevator **24** is used to undermine the scalp **26** anteriorly in a subperiosteal plane and posteriorly in a subgaleal plane as illustrated in FIG. **2**. The anterior dissection may be performed blindly up to a line **28** approximately 2 cm above the level of the brow. As shown in FIG. **3**, a 30 degree 4 mm endoscope **30** is introduced through a scalp incision, and under direct vision the remainder of the forehead **32** is undermined up to the level of the brow **34**. The basic endoscopic brow instrumentation is similar to that used for various endoscopic and arthroscopic procedures, and numerous brow/mid-face endoscopic instrument sets are available to those of ordinary skill in the art. An exemplary endoscope is a 6 or 7 inch, 4 to 5 mm, 30 degree down viewing scope with a halogen light source. A protective sheath for the scope is also preferred.

Next, as shown in FIG. **4**, the dissection is carried out through the temporal incisions **20, 22** medially above the level of the common temporal fascia until the dissection meets with the subperiosteal dissection of the forehead. The frontal and temporal regions are then widely undermined creating a continuous frontotemporal flap **35**. Through the same incision, the periosteum along the lateral orbital rim is elevated to the level of the lateral canthus.

The endoscope **30** is repositioned through a scalp incision, and the periosteum along the supraorbital rim is released by using a curved elevator **36** and a gentle upward sweeping motion as indicated in FIG. **5**. A cautious and meticulous dissection is necessary to avoid injuring the underlying neurovascular structures. Hemostasis may be achieved with an electrocautery device as is known to one of ordinary skill in the art.

At this point, the brows can be moved and rigidly fixed into the desired superior position. As illustrated in FIG. **6**, a single pilot hole **38** may be made through each of the frontal scalp incisions **12–18** using a drill bit **40** on a hand-held power drill **42**. Generally, the drill bit **40** has a diameter **44** of less than 2.0 mm and a stop length **46** of less than 5.0 mm. In one embodiment, the drill bit has a diameter **44** of about 1.7 mm and a 4 mm stop length **46**. The stop **48** on the drill is designed to score the outer cortex of the cranium to allow for a flatter profile of an anchor after insertion. The periosteum **50** surrounding the pilot hole **38** should be fully elevated before drilling begins. The pilot hole **38** is preferably drilled on the posterior edge of the incision after manually placing the forehead flap **35** on maximal tension. This allows for optimal adjustment of the tension of the forehead flap **35**.

Next, one or more suture anchor devices, such as microanchors, are provided. The term "microanchor," as used herein, refers to a device for anchoring sutures within bone having a generally cylindrical body including a first bone contacting end, a second trailing end and bone fixation means formed on at least a portion of an outer surface of the microanchor between the first and second ends. The microanchor has a length of less than about 4.0 mm and has a predetermined length of suture thread attached thereto. Preferably, at least one suture needle is attached to the suture thread.

Generally, two types of microanchors are preferred for use with the method of the invention. One example of a suitable microanchor for use with the method of the invention is a threaded suture anchor **52** illustrated in FIGS. **7–8**. The exemplary threaded suture anchor **52** is substantially cylindrical and has a proximal end **54**, an apex-forming distal end **56** and a sidewall **58** disposed between the proximal **54** and distal **56** ends. The distal end **56** may be self-tapping, or it may simply form an apex which may be threaded into a bore preformed within a bone. The threaded suture anchor **52** used with the system of the invention generally has a major diameter **60** (measured at the widest point of the anchor) of less than about 2.4 mm. More preferably the major diameter **60** of the anchor **52** is about 2.0 mm. The length **62** of the threaded suture anchor **52** is preferably less than 4.0 mm and more preferably is about 3.5 mm.

The sidewall **58** of the threaded suture anchor **52** has at least one external thread **64** suitable for retaining the threaded suture anchor **52** within a bone. The shape of the proximal-most portion **66** of the threaded suture anchor **52** is configured to mate with a suture anchor inserting tool. In the exemplary threaded suture anchor **52**, the proximal-most portion **66**, including external threads on this portion, is in the form of a hexagon.

The threaded suture anchor **52** preferably includes a hole **68** that extends in a direction transverse to a longitudinal axis **70** of the anchor **52**. The hole **68** is useful to seat a

portion of suture thread when the anchor **52** is operatively attached to a suture anchor insertion tool. Longitudinal grooves **72, 74** preferably communicate with the hole **68** and extend proximally therefrom. Longitudinal grooves **72, 74** are useful to seat a length of suture thread, and should be of a sufficient width and depth to seat a length of suture thread while the suture anchor **52** is mated to a suture anchor inserting tool or engaged within a bore in a bone.

An example of one threaded microanchor for use in the present invention is the Mitek® 2.0 mm Tacit™ Threaded Anchor available from Mitek Surgical Products, Inc. of Westwood, Mass. A suitable microanchor installation tool **76** (FIG. **9**) for use with the threaded suture anchor is the Mitek® Tacit™ Inserter, also available from Mitek Surgical Products, Inc. Additional microanchor installation tools useful in the present invention will be readily apparent to one o ordinary skill in the art. One such tool is described in co-pending U.S. patent application Ser. No. 08/870,856, filed Jun. 6, 1997.

Alternatively, the microanchor provided in the present method may be a non-threaded suture anchor **78**, illustrated in FIG. **10**. The non-threaded suture anchor **78** includes a substantially cylindrical body with a proximal end **80**, a distal end **82** forming an apex and a sidewall **84** disposed between the proximal **80** and distal **82** ends. The suture anchor **78** also has two opposed deformable barbs **86, 88** extending from the sidewall **84**. The free ends of the deformable barbs **86, 88** may extend outwardly from the sidewall **84** and proximally (toward the proximal end **80** of the suture anchor **78**) such that each barb defines an angle that is between about 10° and 90° with respect to the sidewall **84**. More or fewer deformable barbs may be provided as desired to ensure proper retention of the suture anchor **78** within a bone. The non-threaded suture anchor **78** may be constructed from a metal such as titanium or a titanium alloy while the deformable barbs **86, 88** are preferably formed from a shape memory material such as nickel-titanium or NITINOL.

The suture anchor **78** further includes a hole **90** that extends in a direction that is transverse to a longitudinal axis **92** of anchor **78**. The hole **90** is useful to seat and retain a portion of suture thread during insertion of the suture anchor **78** into bone. Longitudinal grooves **94** (only one of two shown), which are similar to grooves **72, 74** (FIGS. **7** and **8**), are also provided on the suture anchor **78**. These grooves **94** communicate with the hole **90** and extend proximally therefrom.

When non-threaded suture anchors are used with the system of the invention, such as the barbed suture anchor **78**, the non-threaded suture anchor generally has a diameter **96** of less than about 1.5 mm. More preferably the diameter **96** of the non-threaded suture anchor **78** is about 1.3 mm. The length **98** of the non-threaded suture anchor **78** is typically less than 4.0 mm and more preferably is about 3.7 mm.

An exemplary non-threaded microanchor for use in the present invention is the Mitek® 1.3 mm Micro Anchor available from Mitek Surgical Products, Inc. of Westwood, Mass. An exemplary microanchor installation tool **100** (FIG. **11**) for use with the non-threaded suture anchor is disclosed in U.S. Pat. No. 5,662,658, which is hereby incorporated by reference. One of ordinary skill in the art will readily appreciate that other installation tools may be sued as well.

The microanchor is loaded with suture thread and placed on the end of an inserter. One of ordinary skill in the art will appreciate that suture thread may be constructed from a variety of suture materials. Exemplary materials include, but are not limited to, braided polyester and polydioxanone (PDS).

Once a microanchor **102** and suture thread **104** are properly seated on an inserter **106**, a microanchor **102** is then inserted through each of the predrilled holes on the frontal bone, as shown in FIG. **12**, by turning the inserter in a clockwise fashion until the microanchor **102** is seated at or below the surface of the cranium. Release of the suture anchor **102** will be automatic. The inserter **106** is removed, taking care not to dislodge the suture **104** from the anchor **102**.

Where suture needles have not been preattached to the suture thread **104**, a free end of the suture **104** is threaded through the eyelet of a French-eye needle **108** (FIG. **13**). Starting on the anterior edge of the scalp incision, the suture **104** is passed through the subdermis, galea aponeurotica, and periosteum, taking a generous amount of the soft tissue. The sutures are tied under direct vision while carefully examining the brow for proper positioning. The sutures controlling the lateral brow position should be tied first since these hold the greatest amount of tension. An assistant should support the forehead flap to reduce tension and avoid breaking the suture. After tying all the sutures, a final check for symmetry is made. If needed, an ellipse of full thickness skin is excised from the temporal incision to control for skin laxity and lateral periorbital wrinkling (crow's feet).

To avoid alopecia, all wounds may be closed with a stapling device as known by one of ordinary skill in the art. The wounds are dressed with antibiotic ointment and a snug head dressing is applied. The patient is awakened from anesthesia and delivered to the recovery area. Prophylactic antibiotics and steroids are used according to each surgeon's discretion. The head dressing is removed after 24 hours and no further dressings are necessary. The staples may be removed on the 7th to 10th postoperative day, and the sutures remain in place.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. A surgical procedure for supporting soft tissue of a patient's scalp in a superior position using a suture anchor, comprising the steps of:

making a plurality of incisions proximate to the soft tissue to be moved;

inserting an endoscope through at least one of the incisions;

undermining the soft tissue to be moved while viewing at least a portion of the undermining process through the endoscope;

forming at least one pilot hole in the cranium through one of the incisions;

providing one or more microanchors having a generally cylindrical body including a first bone contacting end, a second trailing end and bone fixation means formed on at least a portion of an outer surface of the microanchor between the first and second ends, the one or more microanchors each having a length of less than about 4.0 mm and having a predetermined length of suture thread attached thereto;

inserting the one or more microanchors into the at least one pilot hole in the cranium;

moving the soft tissue to a desired superior position; and

suturing the soft tissue in the desired position.

2. The procedure of claim 1, wherein the bone fixation means comprise external threads with a major diameter of less than about 2.4 mm.

3. The procedure of claim 2, wherein the microanchor has a length of about 3.5 mm and a major diameter of about 2.0 mm.

4. The procedure of claim 2, wherein each microanchor is constructed from a metal.

5. The procedure of claim 1, wherein each microanchor is removably pre-mated to a suture anchor insertion tool.

6. The procedure of claim 1, wherein the bone fixation means comprises at least one deformable barb capable of penetrating bone tissue.

7. The procedure of claim 6, wherein the microanchor body is composed at least partially of titanium and the deformable barbs are constructed from a shape memory material.

8. The procedure of claim 7, wherein the bone fixation means comprises two opposed deformable barbs capable of penetrating bone tissue.

9. The procedure of claim 6, wherein the microanchor has a diameter of less than about 1.5 millimeters.

10. The procedure of claim 9, wherein the microanchor has a diameter of about 1.3 and a length of about 3.7 mm.

11. The procedure of claim 6, wherein each microanchor is removably pre-mated to a suture anchor insertion tool.

12. The procedure of claim 1, wherein the pilot holes are formed using a drill bit having an effective length of less than about 5 millimeters and having a scoring means suitable to provide clearance around the pilot hole to allow for a suture anchor insertion tool to insert the microanchor at or below the surface of the cranium.

13. The procedure of claim 1, wherein the plurality of incisions include parasagital incisions carried down to the periosteum, are located proximally to the hairline of the scalp and have a length between approximately 1.0 and 2.0 millimeters.

14. The procedure of claim 13, wherein a periosteal elevator is employed to undermine the tissue to be moved.

15. The procedure of claim 13, wherein pilot holes are drilled in a posterior portion of the incisions after manually placing the soft tissue in the desired position.

16. A surgical procedure for supporting soft tissue of a patient's scalp in a superior position using a suture anchor comprising:

making a plurality of incisions proximate to the hairline of the scalp;

undermining the soft tissue to be moved;

moving the soft tissue to a desired superior position;

providing at least one microanchor, pre-loaded with suture thread and removably pre-mated to a suture anchor insertion tool, the microanchor comprising a generally cylindrical body having external threads on at least a portion thereof, having a major diameter of less than about 3.0 millimeters;

forming a plurality of pilot holes in the scalp and corresponding cranium using a drill bit having an effective length of less than about 5 millimeters and having a scoring means suitable to provide clearance around the pilot hole to allow for a suture anchor insertion tool to insert the microanchor at or below the surface of the cranium;

inserting the microanchors into the pilot holes; and

suturing the soft tissue into the desired superior position.

* * * * *

Treatment of Thumb Ulnar Collateral Ligament Ruptures with the Mitek Bone Anchor

Scott H. Kozin, MD

Complete thumb ulnar collateral ligament (UCL) injuries usually require primary repair. The ulnar collateral ligament is often torn from its insertion site and reattachment is difficult. Seven patients underwent repair with the Mitek bone anchor (Mitek Surgical Products, Norwood, MA) for complete ulnar collateral ligament disruptions. A Stener lesion was found in four patients. Follow-up examination was at approximately 1 year. All patients regained a stable metacarpophalangeal joint to valgus stress. X-ray films demonstrated accurate placement of the bone anchor with protraction of the metallic wings within cancellous bone. Range of motion revealed a 7% loss of metacarpophalangeal flexion-extension and a 21% loss of interphalangeal motion. Pinch strength in apposition averaged 98% and in opposition 97% of the uninvolved hand. Grip strength was 96% of the contralateral extremity.

Kozin SH. Treatment of thumb ulnar collateral ligament ruptures with the Mitek bone anchor. Ann Plast Surg 1995;35:1–5

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Thumb ulnar collateral ligament (UCL) injuries are common and require adequate treatment to restore joint stability [1–7]. Complete UCL injuries are frequently avulsed from the site of insertion into the proximal phalanx. Primary repair of the ligament involves secure soft-tissue attachment to the proximal phalanx. A number of methods have been described of performing UCL reattachment, including pull-out wires, connecting drill holes, or direct suture to the periosteum [6, 8–11]. These techniques can be difficult, time consuming, frustrating, or inadequate. We report our experience with the Mitek bone anchor (Mitek Surgical Products, Norwood, MA) to perform open reduction and primary repair of acute UCL injuries.

Materials and Methods

Patient Population

Between 1993 and 1994, seven patients—four men and three women ranging from 20 to 89 years (median, 24 years)—underwent primary repair of complete UCL ruptures with the Mitek bone anchor. The diagnosis of UCL injury was made on the basis of physical examination alone in six patients and supplemented by stress x-ray films after local anesthesia in one (Fig A). Two patients sustained concomitant distal phalanx fractures.

Mechanism of Injury

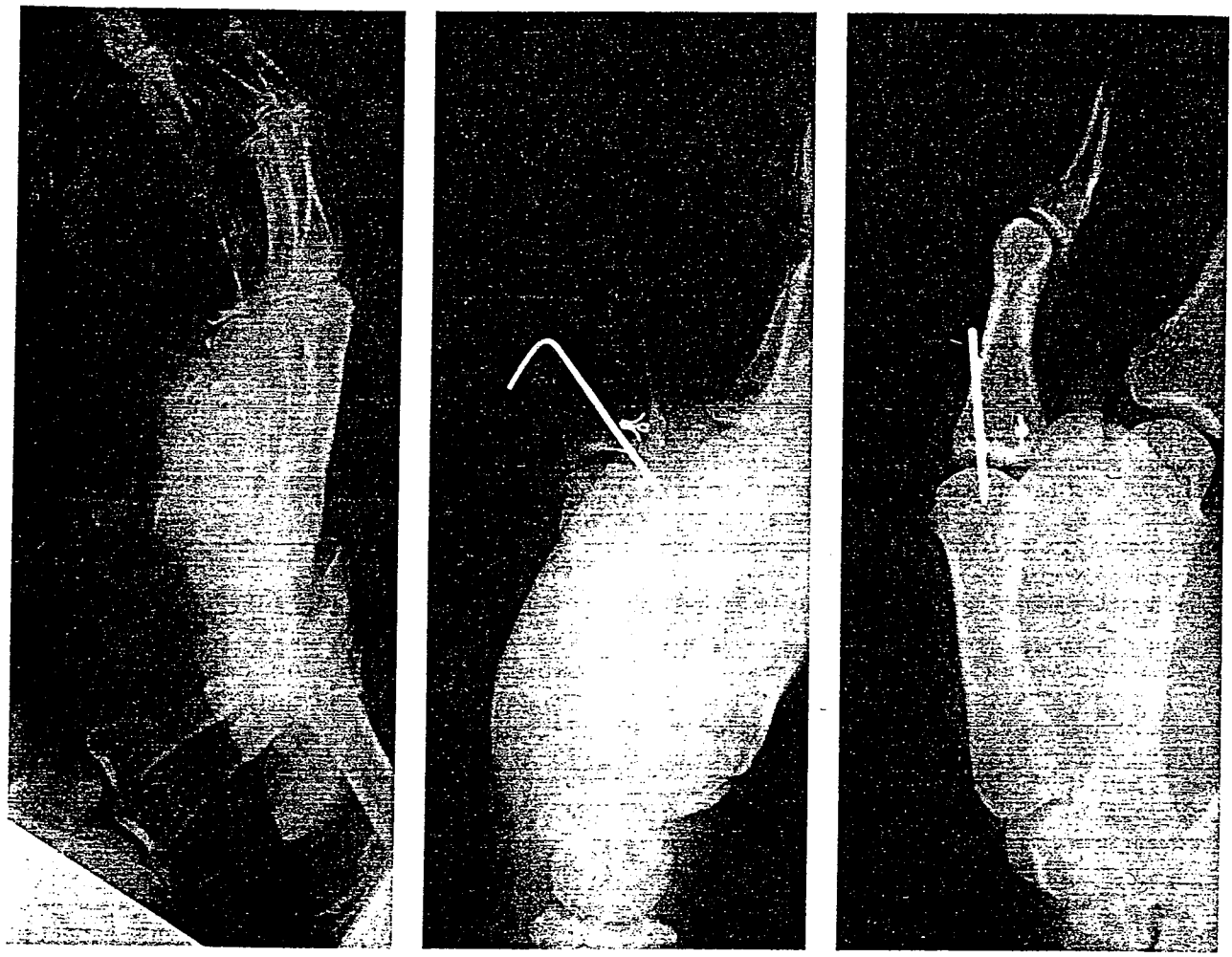
The mechanism of injury involved athletic ventures in six of the seven patients. Five individuals were injured while skiing, one while riding a mountain bike, and one during a fall. All injuries were evaluated and treated within 2 weeks of injury. The average time to surgery was 4 days (range, 2–11 days).

Ligament Injury

The UCL was avulsed from the palmar aspect of the proximal phalanx in all patients. Small flecks of bone accompanied the torn ligament in two patients. These small pieces of bone were excised before ligament repair. No avulsion fractures of significant size were treated with this method. At surgery, a Stener lesion [12] was found proximal to the adductor aponeurosis in four patients (57%) (Fig D).

Operative Technique

Surgery is performed under wrist block anesthesia and tourniquet control. A chevron incision is performed over the thumb metacarpophalangeal (MP) joint. The apex of the incision is located near the UCL insertion site in the thumb-index web space (see Fig D). The skin is elevated, and the radial sensory nerves are carefully preserved. The adductor aponeurosis is incised longitudinally just ulnar to the extensor pollicis longus tendon and elevated from the underlying MP capsule. A longitudinal capsulotomy is performed and the torn UCL visualized. The insertion area

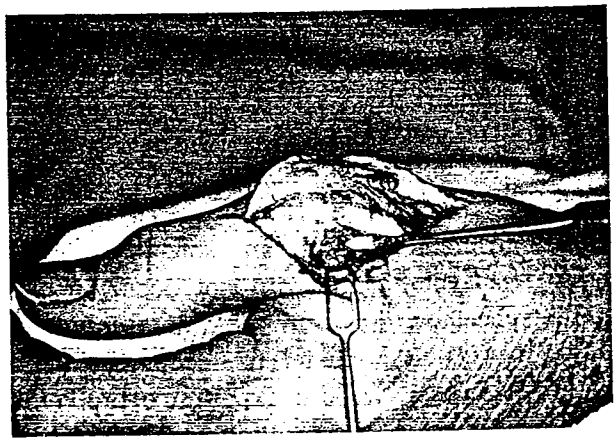


A B C

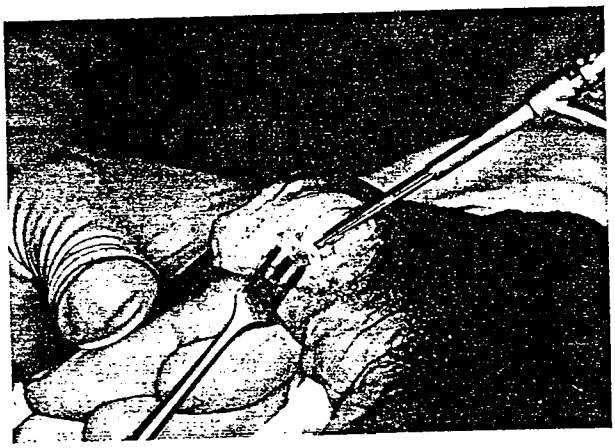
(A) Valgus stress x-ray film confirms complete ulnar collateral ligament (UCL) injury. (B, C) Anteroposterior and lateral x-ray films demonstrate proper placement of bone anchor with protraction of the metallic wings. (D) Chevron incision over the thumb metacarpophalangeal (MP) joint with probe pointing to the torn UCL proximal to the adductor aponeurosis (Stener lesion). (E) Mitek beveled drill bit placed at UCL insertion site at the base of proximal phalanx. (F) Bone anchor inserted into UCL insertion site with attached suture. (G) Layered closure of dorsal capsule and adductor aponeurosis with MP joint pinned in slight flexion and ulnar deviation.

into the base of the proximal phalanx is roughened with a small rasp to promote healing.

The Mitek beveled 1.8-mm or 2.1-mm drill is then inserted at the UCL insertion site until the drill shaft engages the cortex (Fig E). This drill depth allows optimum anchor placement below the cortical surface and creates a beveled surface to avoid cutting the attached suture. The second-generation double-pronged Mitek bone anchor is then inserted with the preassembled 2-0 braided polyester suture. The nickel-titanium alloy bone anchor must be inserted parallel to the drill hole without torque or angulation. A single bone anchor is inserted into the cancellous bone and firmly set by applying tension to the attached suture (Fig F). This engages the metallic wings of the bone anchor into the cancellous bone. The MP joint is then pinned with a percutaneous 0.045-inch Kirschner wire in approximately 20 degrees flexion and slight ulnar deviation. The UCL is then secured to its insertion by passing the attached bone anchor suture through the ligament. The volar plate is repaired to the reinserted UCL to restore accessory collateral ligament function. The dorsal capsule and adductor aponeurosis are carefully repaired, and a thumb spica splint is applied with the interphalangeal (IP) joint free (Fig G). Immobilization is continued for 5 weeks followed by pin removal and range of motion. Abduction stress is avoided for 3 months.



D



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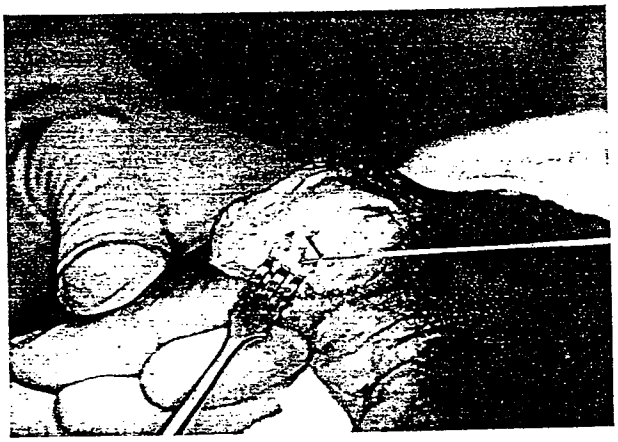
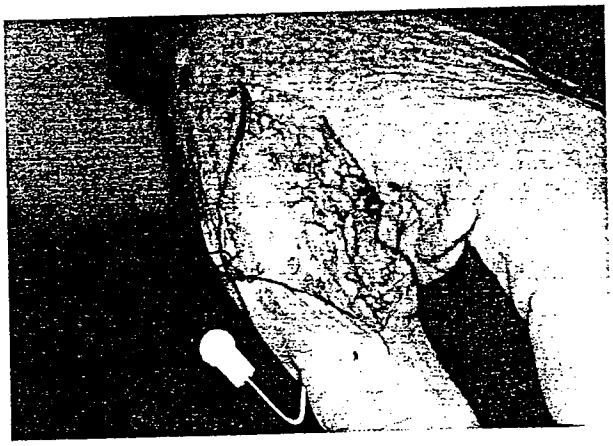


F



G

Fig (continued).

Assessment

The method of evaluation included subjective, objective, and radiographic criteria. Subjective evaluation used the criteria of Derkash and colleagues [13] to assess loss of pinch, pain, and stiffness. Each one of these categories is graded subjectively by the patient as either none, mild, or moderate. Physical examination provided objective measurements of thumb motion and stability. All measurements were performed on the injured thumb and the contralateral thumb. The range of motion was evaluated with a goniometer and the ability to flex and adduct the thumb to the base of the fifth metacarpal recorded. The stability of the UCL was assessed in full extension and 30 degrees of flexion by applying stress. Pinch and grip strength were recorded in kilograms and normalized for dominance by 8%. Radiographs were evaluated for articular changes and status of the bone anchor.

Results

Follow-up averaged 1 year (range, 8–20 months). Loss of pinch, degree of pain, and stiffness was subjectively rated as none in four patients and mild in three. The injured thumb demonstrated firm stability in all patients. There was no excessive laxity or instability on stress testing when compared with the uninjured thumb. No patient complained of prominent hardware or required removal of the implant. All patients were able to oppose their operative thumb to the head of the fifth metacarpal. Range of motion and strength were compared to the contralateral side. MP and IP motion averaged 93% (range, 79–100%) and 79% (range, 74–89%) of the opposite thumb, respectively. Pinch strength recorded with a pinch meter in opposition averaged 97% (range, 93–100%) and in apposition averaged 98% (range, 93–108%) of the uninvolved hand. Grip

strength was 96% (range, 91–106%) of the contralateral extremity. Anteroposterior and lateral x-ray films demonstrated adequate placement of the bone anchor in all patients with protraction of the double pronged metallic wings (Fig B, C). Follow-up x-ray films showed the anchor to remain in position, and no evidence of traumatic arthritis was appreciated.

There were two complications related to the Mitek suture anchor. Both occurred during surgical placement of the anchor after drilling with the 1.8-mm bit. During insertion of the anchor, torque was applied, which caused the anchor to become disengaged from the inserter before complete placement. The anchor did not completely pass through the cortex, and applying nominal tension on the attached suture caused anchor pull-out. Both situations were recognized at surgery and corrected with repeat drilling with the 2.1-mm bit and reinsertion, maintaining axial alignment.

Discussion

Treatment of acute thumb UCL injuries depends on whether a partial or complete lesion is present. Partial tears or sprains can be effectively treated by cast immobilization [11, 14]. Complete ligament injuries require accurate diagnosis and usually require operative measures [3, 4, 8, 12, 13, 15]. Surgery is able to assess the presence of a Stener lesion and repair the UCL. Our diagnosis of complete UCL rupture was based on physical examination alone in the vast majority of cases and supplemented by stress x-ray films after local anesthesia in one patient, with significant adductor spasm hindering examination. Surgery confirmed the complete UCL injury in all cases and located a Stener lesion in four instances (57%) that would have prevented healing.

Repair of the UCL to bone can be accomplished by a number of methods. An exact method for affixing soft tissue to bone has remained elusive. The Mitek bone anchor facilitated repair by avoiding the need for connecting drill holes, pull-out sutures, and external buttons. The use of the Mitek bone anchor for fixation of thumb UCL injuries was initially the subject of a case report [16]. Subsequently, the application of the single-pronged first-generation Mitek bone anchor to treat ligament injuries of the upper extremity has been reported [17].

Complications noted were penetration of the distal cortex with the anchor when the device is applied to small-caliber bones. This caused prominent metal hardware and soft-tissue problems. This complication did not occur in our patients because the thumb proximal phalanx was of sufficient diameter to accept the bone anchor. However, we did experience problems with the insertion of the Mitek bone anchor in two patients in whom torque was applied during insertion, which prevented anchor placement through the cortex into the cancellous bone. The cortex prevented the metallic wings from extending, and anchor pull-out occurred during surgery. The use of the 2.1-mm drill instead of the 1.8-mm bit allowed easier insertion with less force and decreased the chances of the anchor being captured in the cortex. According to Mitek Surgical Products, the insertion force decreases from 20 to 7 pounds when the larger 2.1-mm drill is used without affecting pull-out strength.

X-ray film analysis demonstrated fixation of the Mitek bone anchor within the cancellous bone and protraction of the metallic wings. Follow-up examination revealed comparable stability to the uninjured thumb and no instability to valgus stress. Because of the great variability in thumb range of motion between individuals, accurate assessment of postoperative motion requires direct comparison with the uninjured thumb [18, 19]. In our patients, there was a slight loss of motion at both the MP and IP joints compared with the contralateral thumb. However, pinch and grip strength were restored after UCL repair. Previous studies have reported similar findings with return of strength but decreased motion after fixation of thumb UCL injuries [6, 20]. The favorable clinical outcome combined with the advantages of the Mitek bone anchor encourage us to recommend this technique for fixation of complete UCL ruptures at the thumb MP joint.

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Endoscopic Brow Lifts

Keith F. Brewer, M.D. • Davis, California

The essence of plastic surgery is creativity. Many other disciplines have adapted techniques developed and perfected by plastic surgeons. In turn, plastic surgery has been able to adapt technology from other medical specialties. Endoscopy, long utilized by other medical and surgical disciplines, is a relative newcomer to current plastic surgical techniques. It has been used in anatomic areas in which spaces exist, e.g., the peritoneal cavity, joints, and hollow viscera. It was only a matter of time until it was creatively applied to soft tissue surgery. Pioneering work by Vasconez, Isse, Daniels, Ramirez and the Emory group have demonstrated the usefulness of endoscopy in both aesthetic and reconstructive surgery. Yet not all practitioners concur, indeed one was overheard expressing the opinion that "an endoscope was an instrument looking for an operation".

One of the areas which has enjoyed immediate application of these techniques is that of the brow and periorbital area. Certainly few surgeons would dispute the desirability of upper facial rejuvenation. While that area is well served by open coronal and anterior hairline incisions, patients dissatisfaction certainly did occur with the scalp scars and their visibility, alopecia and sensory disturbances. Though some practitioners, e.g. Connell, have demonstrated great facility in avoiding these pitfalls, most others have been less fortunate. That combined with the extensive scalp incision has made some patients who really could use brow elevation decline to proceed asking, "Isn't there any other way, doctor?" Well, there is and it works!

The basic Endoscopic brow lift technique is well described and illustrated by Daniels in the ASPRS Video #1. Dr. Daniels has made several important modifications which have increased the ease of the procedure and improved his results. He now uses five scalp incisions instead of six, combining the two medial incisions into one central incision. The lateral scalp incision above the lateral canthus is angled 30 degrees, providing more lateral eyebrow elevation giving a more fashionable eyebrow shape.

It is important to understand that endoscopic equates with minimal incisions and not minimal surgery. The extent of the dissection, the periosteal release, the muscle modification is as extensive as in the open brow procedure. What is missing is the skin resection. Elevation and fixation of the brow is provided by deep temporal fascia sutures and Mitek anchors. This requires some scalp shrinkage and this generally occurs without difficulty except in cases with profound ptosis and skin excess. Often those are better suited for the open technique.

The basic endoscopic brow instrumentation is similar to that used for knee arthroscopy. While numerous companies, Snowden Pencer, Wells Johnson, Byron Medical, Padgett and Storz, to name a few, have complete endoscopic brow/mid-face instrument sets, the initial investment can be intimidating, in this era of cost constraint. One needs at the onset a 6 or 7 inch, 4 to 5 mm, 30 degree down viewing scope with a halogen light source - the brighter the better. A protective sheath for the scope is essential, quarter and half curved, scalp orbital rim elevators, right and left handed scissors, and a grasping forceps complete the basic setup.

The beauty of the procedure is in its unparalleled flexibility. While open procedures are quite adjustable, once the tissue is excised, the surgeon has committed his or herself. With the endoscopic browlift, the surgeon is able to adjust readily the amount of advancement

continued on page 15

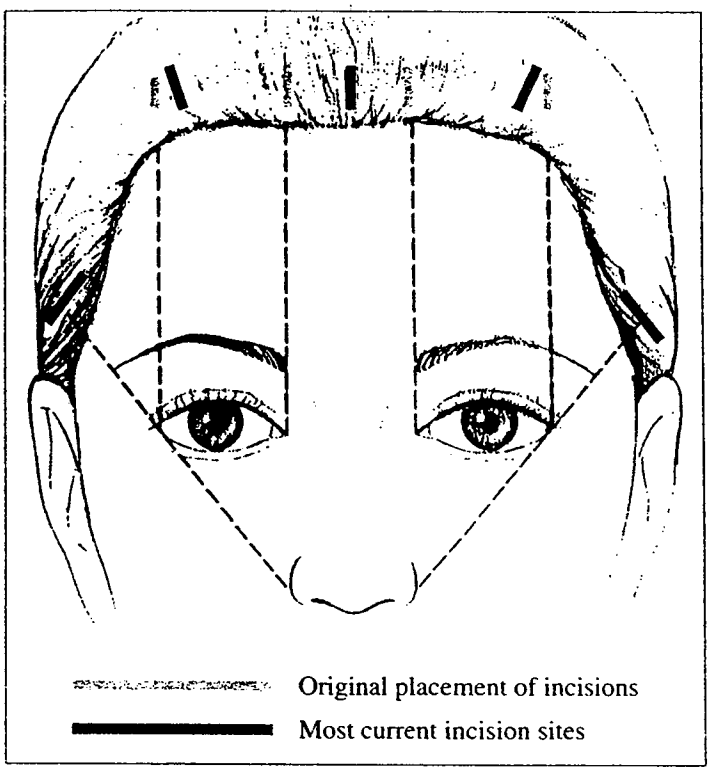
Endoscopic Brow Lifts

Continued from page 13

releasing or advancing around the fixation points. While it is possible to generate the open stare or surprised, startled look, it is more difficult because of the inherent adjustability of the technique.

To that end, what are the goals of any browlift? One seeks to elevate the eyebrow/periorbital complex particularly in its lateral extent, to soften or eliminate glabellar furrows and periorbital rhytides. How much is enough?... classically.

Once the dissection is completed and the amount of elevation decided upon preoperatively is confirmed intraoperatively, the surgeon should use some fixation to prevent early post operative slippage. Laterally in the temporal area, ethibond sutures are placed between the deep temporal fascia and the galea to secure the advancement. Ethicon makes a very nice 2-0 ethibond on a UCL needle which is ideal for this.



Fixation over the central two thirds of the dissection, i.e. the skull, has been problematic. Some practitioners have felt that the periosteal/periorbital and anterior muscle release provided sufficient elevation to obviate the need for fixation. What I have found far more preferable is a **Mitek Tacit Threaded Anchor**. This is a 2mm self tapping version of the larger fixation device commonly used in orthopedic surgery. The anchor is placed in the outer table of the skull after drilling and counter sinking a hole using a custom drill bit. This generates a hole in the outer table of the skull of a reproducible depth which is chamfered and counter sunk in its upper one third allowing the anchor to sit flush with the skull. A 3-0 ethibond suture looped through the top of the anchor allows the scalp advancement to be secured via galeal sutures. Fixation and elevation has been maintained without slippage. It is however not adjustable in the post operative period as is the outer table screw technique. I have noted less alopecia and scar depression since introducing this into my practice.

Another useful device is the **Guyuron Access Port**. These are made of soft silicone rubber and consist of a slanted tunnel with wide flanged ends. One flange is positioned subgaleally and the other is on the skin. As the flanges are offset, the tunnel angles anteriorly allowing ease of introduction of the endoscope into the operative field without getting covered by ooze, hair and other wound debris. It makes the surgeon less dependent upon his assistant and speeds the completion of the case as less time is spent cleaning the scope.

Lastly, the department of technique, I have been doing, in addition to supra orbital and supra trochlear nerve blocks, blocks of both the occipital and zygomaticotemporal nerves with 0.5% marcaine with epinephrine. Though I do all these surgeries under general anesthesia due to patient choice, these blocks have provided profound post operative analgesia resulting in happy patients.

In conclusion: In my experience, I have found the **Guyuron Access Ports** and the **Mitek Tacit Threaded Anchors** invaluable tools that have improved the ease of performing my Endoscopic Brow Lifts; not only saving time, but also increasing the safety of the procedure. Using the custom drill bit which stops at a certain depth provides a sense of security especially for those operating in their own offices.

In reviewing magazines and noting that the more aesthetically pleasing brow arches more laterally than centrally, I have changed the advancement to a less medial pull and more lateral, outward pull. I hope that these observations and personal experiences will be of some help to others including endoscopic brow lifts in their facial rejuvenation procedures.

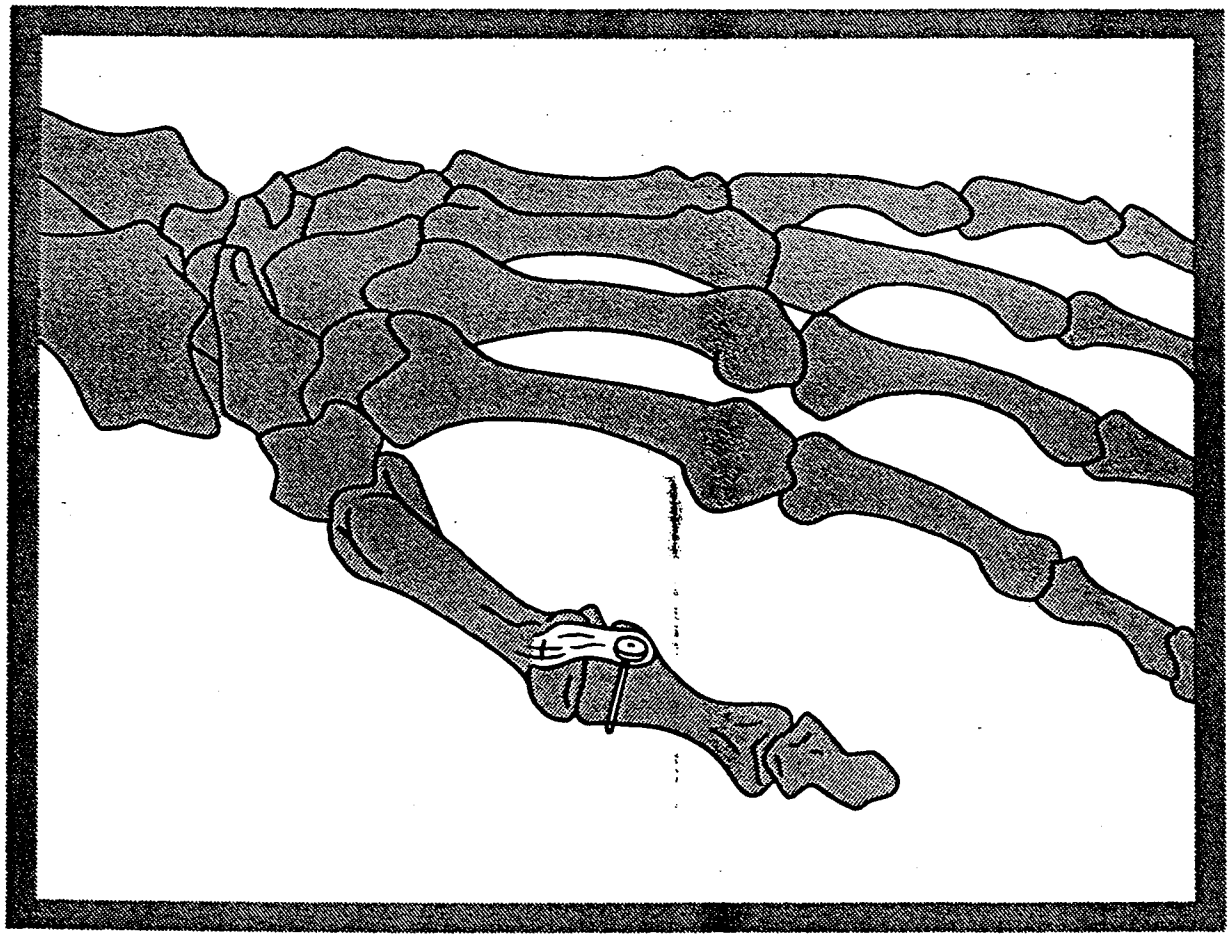
I find myself automatically offering it with all standard facelifts and have been very pleased with the results. ■

BIOFIX® LIGAMENT TACK

BIODEGRADABLE LIGAMENT INJURY FIXATION TACKS

SURGICAL TECHNIQUES I

Treatment of injuries of ulnar collateral ligament of thumb with a biodegradable mini-tack



BIOFIX® LIGAMENT TACK

BIODEGRADABLE LIGAMENT INJURY FIXATION TACKS

SURGICAL TECHNIQUES I

Treatment of injuries of ulnar collateral ligament of thumb with a biodegradable mini-tack

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1990

Contents

1. INTRODUCTION

Biodegradable BIOFIX® tacks* are intended for the treatment of ligament ruptures. The first clinical device, BIOFIX mini-tack is intended for treatment of complete ruptures of ulnar collateral ligament of thumb. The mini-tack is driven into the predrilled channel in bone through the ligament to keep ligament in its place during healing.

The raw-material of BIOFIX tacks is self-reinforced poly-L-lactide (SR-PLLA), which has been shown to be highly biocompatible in both animal and clinical evaluations.

SR-PLLA BIOFIX mini-tacks comprise the cylindrical shaft with the length of 15 mm and the nominal diameter of 1.1 mm corresponding to a standard bone drill size (1.1 mm). The proximal end of the mini-tack comprises the flat top with the diameter of 4 mm and the thickness of 0.5 mm. Figure 1 shows as enlarged a BIOFIX mini-tack.

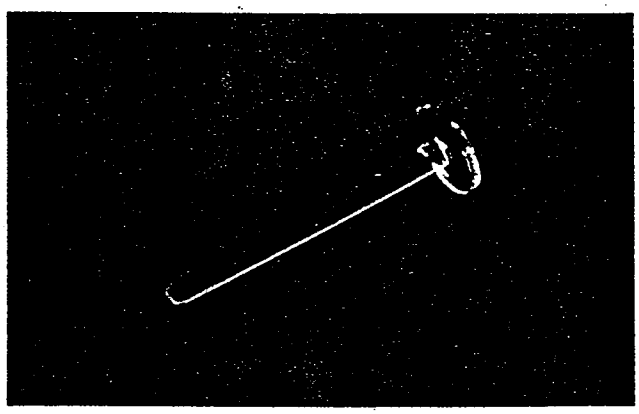

Figure 1. BIOFIX mini-tack (magnification x 3).

The actual diameter of shaft of mini-tack exceeds somewhat (0.05—0.1 mm) that of standard bone drill size. This produces strong frictional locking forces when the tack is pushed into the drilled channel in bone.

2. MATERIAL AND ITS PROPERTIES

BIOFIX mini-tacks are constructed of patented, self-reinforced polylactide (SR-PLLA) composite material (Törmälä et al. 1988). A very high initial mechanical strength is typical to this material, even corresponding to the yield strength of stainless steel. The tacks lose their strength by biodegradation and shift more and more stress from the tack to the healing ligament tissue. Eventually, after healing of the ligament, the tacks are digested by living tissues so that no removal operation is necessary. Table 1 gives initial strength values of BIOFIX mini-tacks.

Table 1. Strength properties of BIOFIX mini-tacks

Property	Value
Bending strength of the shaft	250±50 MPa
Bending modulus of the shaft	8—9 GPa
Shear strength of the shaft	200±20 MPa
Tensile load carrying capacity of the top	140 N

The mini-tack retains its strength ca. 6—12 months in vivo and absorbs in ca. 2—4 years.

3. STERILIZATION OF BIOFIX MINI-TACKS

SR-PLLA BIOFIX mini-tacks are sterilized by γ-radiation. Resterilization by any method is not recommended. Repeated gas sterilization (with ethylene oxide, formaldehyde etc.) or repeated radiation sterilization (with α-, β- or γ-radiation etc.) causes degradation of this material. Chemical sterilization (with alcohol, desinfection chemicals etc.) may damage the structure of the material.

4. CLINICAL PROPERTIES OF BIOFIX MINI-TACKS

— Tissue irritation, sometimes caused by corrosion of metallic threads, is eliminated.

— Mini-tacks will stabilize the ligament injury during the healing period and biodegrade gradually, shifting more and more stress from the fixation device to the healing tissues.
— The BIOFIX mini-tacks biodegrade into small molecules, which are totally metabolized, without causing tissue reactions which should prevent the ligament healing.
— THE BIOFIX MINI-TACKS ARE ABSORBABLE, THUS ELIMINATING THE NEED FOR REMOVAL OF THE IMPLANT.

— Anaesthetic risks and costs per patient are reduced with the elimination of a second operation.
— Strong frictional forces between the shaft and the wall of the drilled channel caused by the somewhat exaggerated diameter of the tack shaft produce a tight fixation which prevents sliding of the implant.
— The shaft can easily be cut with a bone saw or with a heated (T 250°C) scalpel blade or wire.
— The flat geometry of the top leads to avoiding protruding prominences under the skin.
— After absorption of the material the risks of long term complications are eliminated.
— Cost/patient is reduced.
— The efficiency of the use of hospital personnel is increased.
— Operation capacity can be shifted to other operations, which shortens the operation lines.
— The risks of patients are decreased.
— The need of sick-leave is decreased.

5. INDICATION AND RESTRICTION FOR THE USE

Indication for BIOFIX mini-tack is clinically tested total instability of the ulnar collateral ligament of the first metacarpophalangeal joint which reduces the pinch grip leading to the insufficiency of the hand.

The use for patients younger than 16 years is not recommended because the effect of the mini-tack on the physis of the proximal phalanx has not yet been studied.

6. OPERATING TECHNIQUE

Bloodless field should be used with intravenous anesthesia. Dorsoulnar light S-shaped incision is made. The dorsal sensory branch of the interdigital nerve is pushed ulnarily and the adductor aponeurosis is opened sharply. The ligament is identified. The metacarpophalangeal joint is opened for the identification of the joint surfaces. A drill channel of 1.1 mm in diameter is drilled perpendicularly to the axis of the proximal phalanx 3—4 mm from the joint surface distally. If the rupture is proximal the channel is drilled in the same way into the head of the first metacarpus. Kirschner wire of 1.1 mm in diameter is used for the channeling of the ligament (Fig. 2). The channel is placed into the ligament at least 3—4 mm from the ruptured end of the ligament. BIOFIX mini-tack is pushed through the ligament into the bone channel (Fig. 3.).

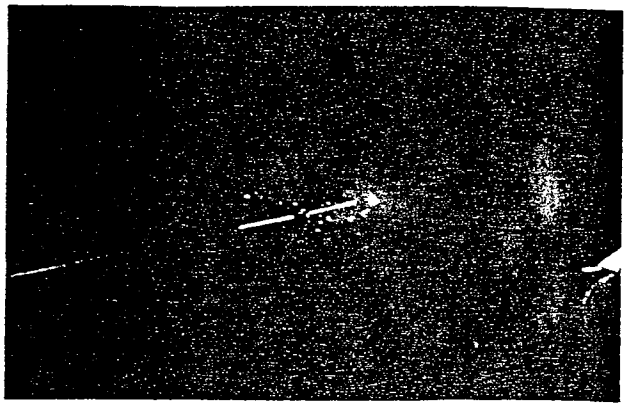

Figure 2. The channeling of the ligament with a Kirschner wire (diam. 1.1 mm).

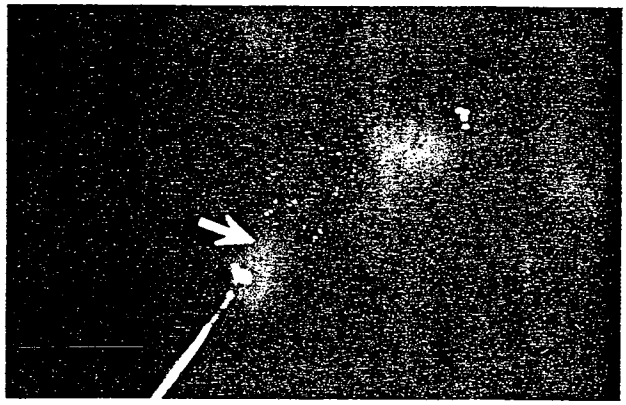

Figure 3. BIOFIX mini-tack (see arrow) has been pushed through the ligament into the bone channel.

The top of the tack is pressed tightly against the cortex (Fig. 4). The stability of the MCP I joint is checked (Fig. 5). Usually the implant stabilizes the joint immediately. The aponeurosis is sutured to cover the top of the tack.

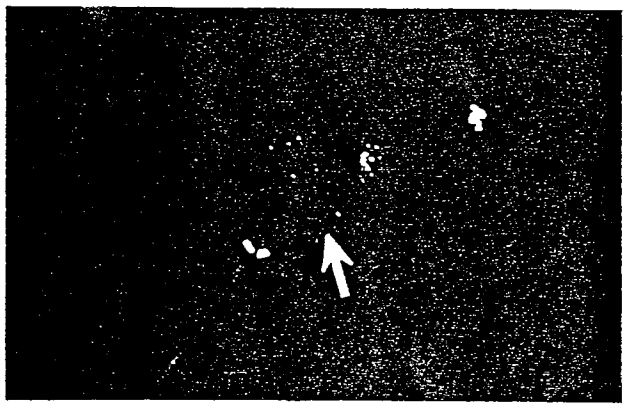

Figure 4. The top of the tack (see arrow) has been pressed tightly against the cortex.

Figure 5. The stability of the MCP I joint is checked.

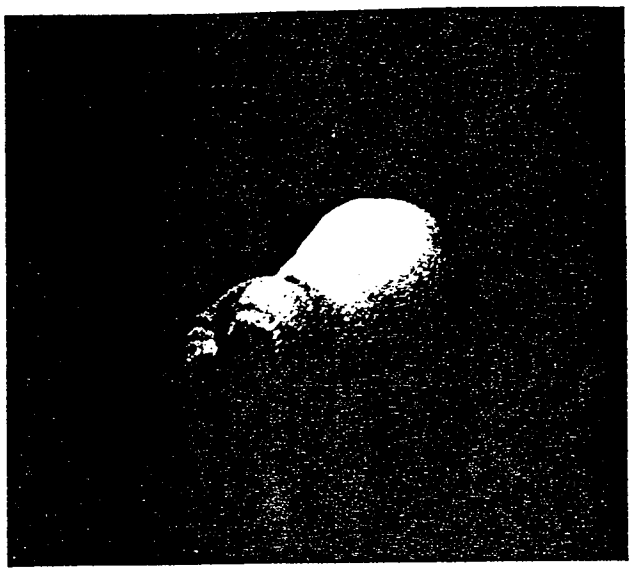

Figure 6. The plaster cast immobilizes the injured ligament postoperatively.

7. POSTOPERATIVE COURSE AND FOLLOW-UP

The dorsal plaster cast from the middle of the distal phalanx to the proximal third of the forearm immobilizes the injured ligament postoperatively for four weeks (Fig. 6). The plaster is changed after two weeks and the sutures are removed. The mobilization is started after four weeks immobilization and the motion of the thumb is controlled six weeks postoperatively.

When absorbable implants are used, in some patients a postoperative, nonbacterial, local fluid accumulation (swelling) may develop in a primarily uneventfully healed wound even many months after operation. The patients should be informed of the possibility of the fluid accumulation so, that they can contact the doctor if fluid accumulation develops. If it is red and painful, it should be treated by needle aspiration with 1.1 mm needle. Needle aspiration may be repeated, if necessary. An incision is an alternative for aspiration. After treatment the healing is completed normally in a few weeks.

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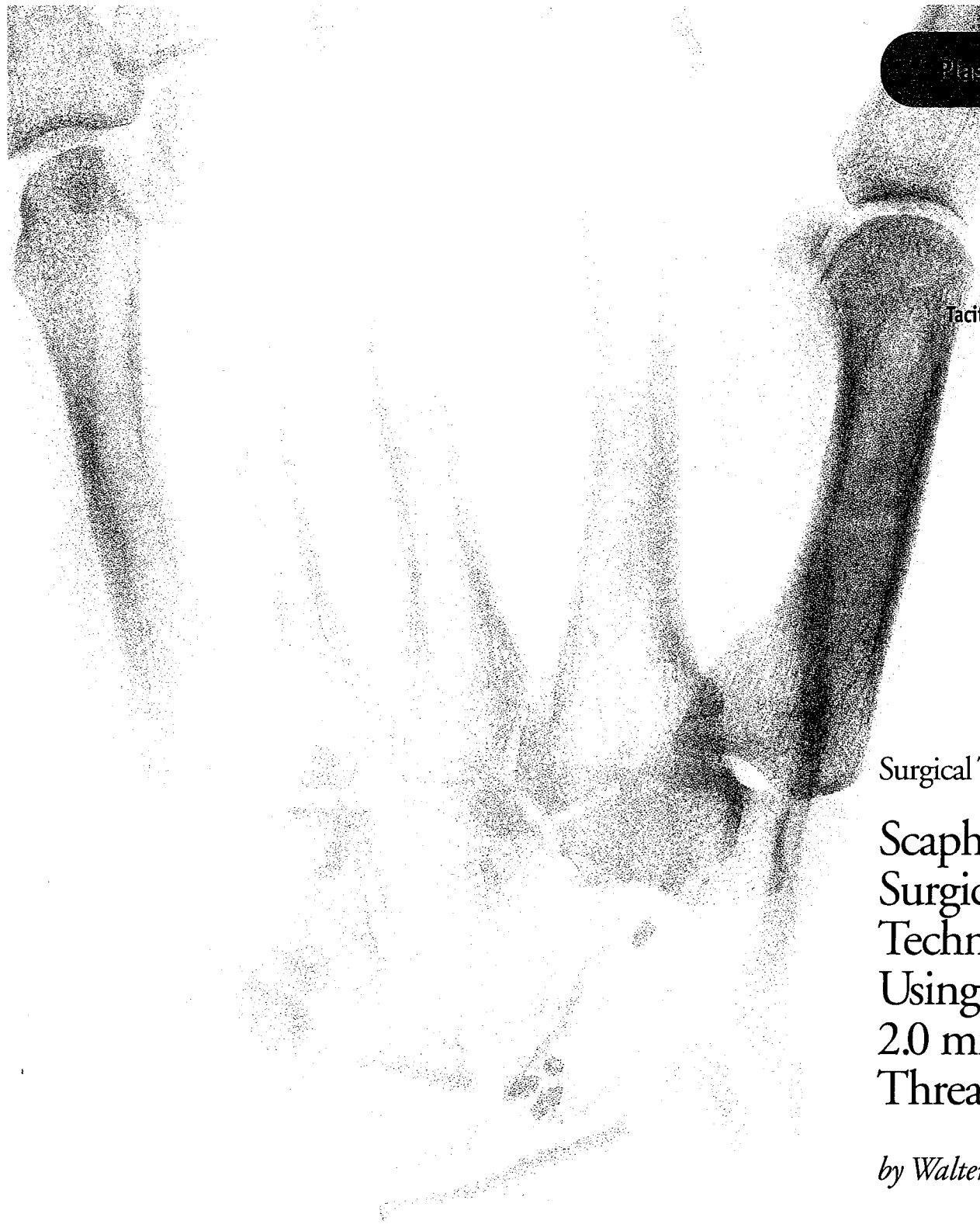

Plastic / Orthopedic

Mitek 2.0 mm
Tacit™ Threaded Anchor

Surgical Technique:

Scapholunate Surgical Technique Using the Mitek 2.0 mm Tacit™ Threaded Anchor

by Walter H. Short, M.D.

Mitek®

Scapholunate Surgical Technique

Using the Mitek 2.0 mm Tacit™ Threaded Anchor

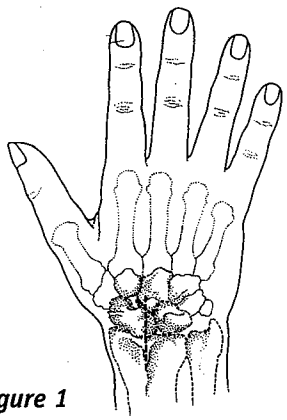

Figure 1

Complete tears of the scapholunate interosseous ligament (SLIL) can lead to instability of the carpus. This injury most commonly occurs by longitudinal force on the outstretched hand. Patients present in the office with pain, swelling and occasional clicking within the wrist. On physical examination, there is usually a swelling over the dorsum of the wrist. Palpation of the wrist reveals pain that is centered over the scapholunate interval, which is distal and slightly ulnar to Lister's tubercle. If these symptoms persist, then an evaluation is warranted. Plain x-rays and wrist motion studies may either be normal or show a dorsal intercalated segment instability pattern. Another finding on the x-ray may be an abnormal gap between the scaphoid and lunate. Triple compartment arthrograms in many cases may confirm the clinician's suspicion that there is a tear of the SLIL. Diagnostic arthroscopy of the radial carpal joint can confirm a tear of the SLIL. This tear typically is seen as a detachment of the ligament from its insertion into the scaphoid. Arthroscopic assessment should also confirm that the ligament can be repaired. Midcarpal arthroscopy can assess the degree of instability between the scaphoid and lunate. Surgical repair is indicated when clinical symptoms persist in spite of immobilization and activity modification, and workup of this problem reveals a repairable tear of the scapholunate ligament. Other causes of wrist pain should be ruled out.

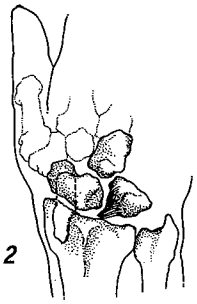

Figure 2

One method of surgical repair of this lesion is to suture the SLIL back to the bone by means of drill holes placed through the scaphoid, as well as doing a dorsal capsulodesis to the scaphoid by using pull-out wires. These surgical procedures have been described by Blatt[1] and Lavernia et al.[2] This operation can be facilitated by the use of the Mitek 2.0 mm Tacit Threaded Anchors.

Surgical Procedure

A 6-8 cm longitudinal incision is made over the dorsal aspect of the wrist. This incision is centered over the Lister's tubercle ***(Figure 1)***. The subcutaneous veins are coagulated. The extensor retinaculum is then identified and the third dorsal compartment is located. An incision is made through the extensor retinaculum and is then reflected radially and ulnarward. The extensor tendons are then retracted, exposing the dorsal capsule of the wrist. The wrist is then flexed and the scaphoid, lunate and scapholunate interval can be palpated. Two longitudinal incisions are made in the dorsal capsule approximately 1 cm apart, centered over the central portion of the scaphoid. These incisions are connected distally at the level of the distal pole of the scaphoid. This creates a proximally based capsular flap that will be used for the dorsal capsulodesis portion of the procedure ***(Figure 2)***. The dorsal wrist capsule ulnar to this flap is carefully dissected and separated from the SLIL. When this portion of the procedure is complete, the dorsal aspect of the scaphoid and lunate

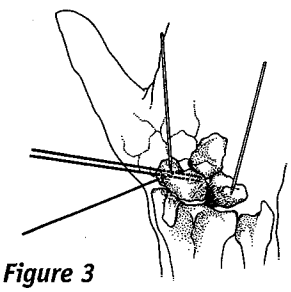

Figure 3

should be well visualized and the torn SLIL should also be seen. In the majority of cases, the ligament remains attached to the lunate and is avulsed from the scaphoid. Two .062 in. K-wires are then inserted from dorsal to volar, one into the scaphoid and the other into the lunate. These then act as joysticks to manipulate the scaphoid and lunate. A C-arm is then brought into the surgical field and under fluoroscopic control, two .045 in. K-wires are inserted percutaneously through the anatomic snuffbox. The K-wires are then drilled through the scaphoid and directed so as to pass through the scapholunate joint and into the lunate. These K-wires are left in the subchondral bone underneath the articular surface of the scaphoid at the scapholunate joint. A third .045 in. K-wire is inserted through the snuffbox, but directed through the scaphoid toward the body of the capitate. At this point in the procedure, this K-wire is left in the scaphoid and should not traverse the scaphocapitate joint ***(Figure 3)***.

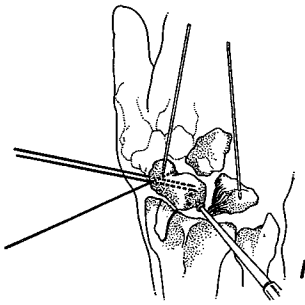

Figure 4

At this juncture, the wrist is flexed and the scapholunate joint distracted by use of the joysticks. The insertion of the SLIL where it was avulsed from the scaphoid is debrided to subchondral bone. Three drill holes are made into the prepared site on the scaphoid with the Mitek 1.7 mm anchor drill. These drill holes are placed so that one is in the dorsal aspect of the scaphoid, one is in the midportion of the ligament and the third is in the volar portion of the ligament ***(Figure 4)***. The anchor is then prepared and a 3-0 suture is placed on the anchor. The 2.0 mm Tacit™ Threaded Anchor is then inserted into the prepared drill hole in the scaphoid ***(Figure 5)***. The sutures are placed through the ligament by the use of free needles. The sutures are positioned so that the knots are on the proximal surface of the ligament. After the sutures are placed, the wrist is extended to neutral ***(Figure 6)***. Under fluoroscopic control, the scapholunate interval is reduced and the two K-wires are passed across the scapholunate joint into the lunate. Fluoroscopy should confirm that there is no gap between the scaphoid and lunate, no malrotation between the two carpal bones and the anchors are positioned appropriately. The wrist is then flexed and sutures in the SLIL are then tied so as to appose the ligament to the subchondral prepared bone of the scaphoid ***(Figure 7)***. The C-arm is then used and the position of the scaphoid is reduced by means of the joysticks, so that a normal relationship between the scaphoid, lunate, radius and capitate is maintained. When this is confirmed on the C-arm, the third K-wire, which was previously inserted, is advanced across the scaphocapitate joint into the capitate. Further fluoroscopic views should confirm that normal anatomic relationships have been restored and that the K-wires are appropriately placed. The .062 in. K-wires that were used for joysticks are then removed.

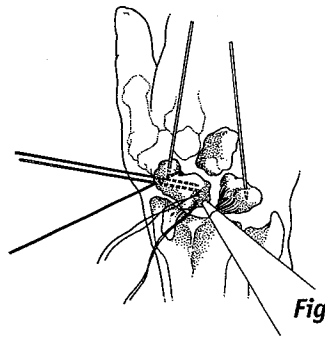

Figure 5

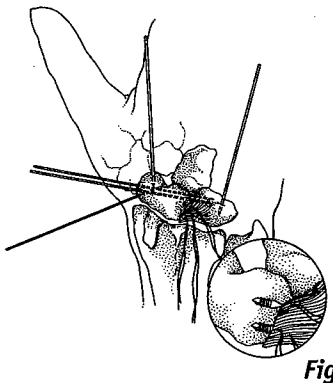

Figure 6

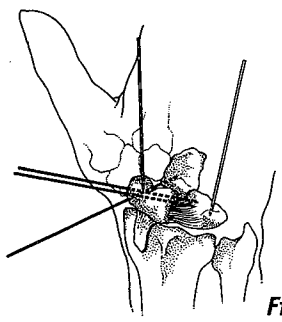

Figure 7

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The First Name In Suture Anchors.™

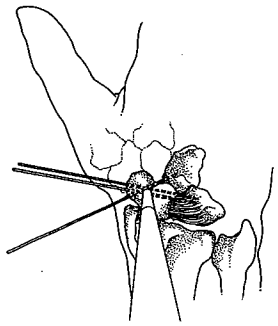

Figure 8

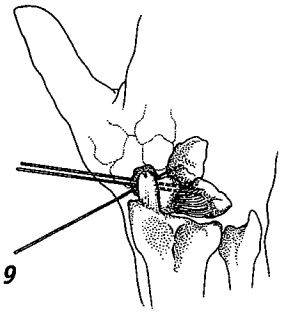

Figure 9

Another Mitek 2.0 mm Tacit™ Threaded Anchor is prepared using 3-0 suture. This anchor is placed in the distal dorsal aspect of the scaphoid just proximal to the distal pole of the scaphoid ***(Figure 8)***. The suture is then passed through the previously prepared dorsal capsular flap. The suture is placed so that when the capsular flap is brought down to the insertion site of the anchor, it is taut. The suture is then tied thus creating a capsulodesis, as described by Blatt[1] ***(Figure 9)***. The remaining dorsal capsule is then closed with nonabsorbable sutures. The extensor retinaculum is then repaired back to itself using absorbable sutures. The tendon of the extensor pollicus longus is left out of the extensor retinaculum to facilitate closure of this structure. The subcutaneous tissue is then closed and the skin is closed following this. The K-wires that were used to hold the position of the carpal bones are then cut and left protruding through the skin. At the end of this procedure, a sugartong splint is applied.

Approximately one week after the procedure, the patient is brought back to the office, the sutures are removed and the patient is placed in a thumb spica muenster cast. This cast is left on for three weeks. The cast is then changed to a short arm thumb spica cast. The patient is kept casted for a period of eight weeks from the time of surgery. At the end of this immobilization period, the patient is sent to physical therapy for a progressive rehabilitation program that initially includes active exercises and then gradually progresses to passive and resistive exercises and strengthening.

References:

1. Blatt G. Capsulodesis in reconstructive hand surgery: dorsal capsulodesis for the unstable scaphoid and volar capsulodesis following excision of the distal ulna. *Hand Clinics.* 3:81-102, 1987.

2. Lavernia CJ, Cohen MS, Taleisnik J. Treatment of scapholunate dissociation by ligament repair and capsulodesis. *J Hand Surg.* 17 (2) : 354-9, 1992.

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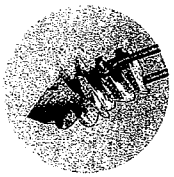
Plastic/Reconstructive



Mitek 2.0 mm
Tacit™ Threaded Anchor

Surgical Technique:

Endoscopic Browlift with Rigid Fixation Using the Mitek 2.0 mm Tacit™ Threaded Anchor

by Eduardo Barroso, MD
Thomas Mustoe, MD

Mitek®

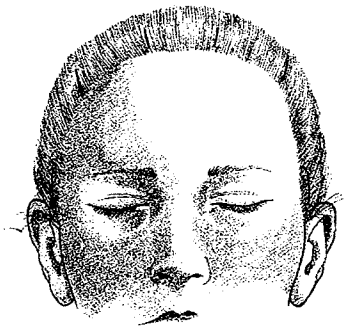


Figure 1

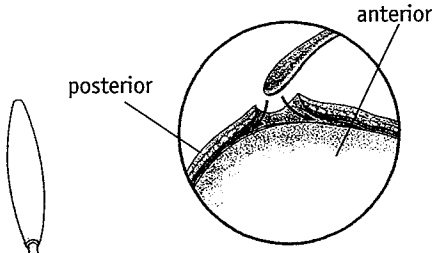


Figure 2

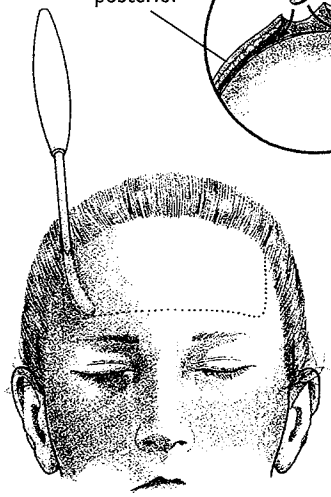


Figure 3

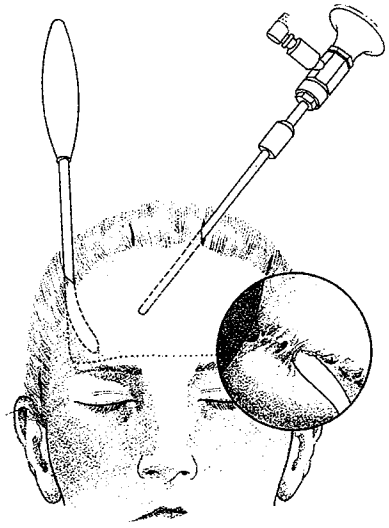


Figure 4

Endoscopic Browlift with Rigid Fixation

Using the Mitek 2.0 mm Tacit™ Threaded Anchor

The patient is brought into the operating room where either general or IV sedation anesthesia is administered. The face and scalp are cleansed with an antiseptic solution and draped under sterile technique. Two medial parasagital and two lateral brow incisions, approximately 1 cm proximal to the hairline and 1.5 to 2.0 cm in length, are used as portals of entry for the endoscope. Bilateral temporal scalp incisions are made to allow access of the temporal parietal region. These incisions start approximately 1 cm above the root of the helix of the ear and extend superiorly 3 cm. ***(Figure 1)*** The scalp incisions are infiltrated with a 1% lidocaine and 1:100,000 epinephrine solution. The remainder of the scalp is infiltrated with a dilute local anesthetic, according to personal preference.

The incisions on the scalp are then made and carried down to the periosteum. A periosteal elevator is used to undermine the scalp anteriorly in a subperiosteal plane and posteriorly in subgaleal plane. ***(Figure 2)*** The anterior dissection is performed blindly up to approximately 2 cm above the level of the brow. ***(Figure 3)*** A 30 degree 4 mm endoscope is introduced through the scalp incision, and under direct vision the remainder of the forehead is undermined up to the level of the brow. ***(Figure 4)*** Through the temporal incisions, the dissection is carried medially above the level of the common temporal fascia until it meets with the subperiosteal dissection of the forehead. ***(Figure 5)*** The frontal and temporal regions are now widely undermined creating a continuous fronto-temporal flap. Through the same incision, the periosteum along the lateral orbital

rim is elevated to the level of the lateral canthus. The endoscope is repositioned through the scalp incision, and the periosteum along the supraorbital rim is released by using a curved elevator and a gentle upward sweeping motion. The supraorbital and supratrochlear neurovascular pedicles can be easily identified with this maneuver. ***(Figure 6)*** If a corrugator or procerus muscle resection is indicated, a grasper can be used to gently avulse these muscle fibers. A cautious and meticulous dissection is necessary to avoid injuring the underlying neurovascular structures. Hemostasis is obtained with electrocautery. The brows can now be moved and rigidly fixed into the position of choice.

A single pilot hole is made through each of the four frontal scalp incisions using a 1.7 mm Tacit™ drill bit with a 4 mm stop on a hand-held power drill. ***(Figure 7)*** The 4 mm stop on the drill is designed to score the outer cortex of the cranium to allow for a flatter profile of the anchor after insertion. It is crucial that the periosteum surrounding the pilot hole be fully elevated before drilling begins. The pilot hole must be drilled on the posterior edge of the incision after manually placing the forehead flap on maximal tension. This allows for optimal adjustment of the tension on the suture and forehead flap. The Mitek 2.0 mm Tacit Threaded Anchor is loaded with 2-0 suture and placed on the end of the inserter according to the manufacturer's instructions. The inserter is designed to protect the suture during insertion. Thus, care must be taken to ensure that the anchor is properly seated on the inserter. The anchor is then

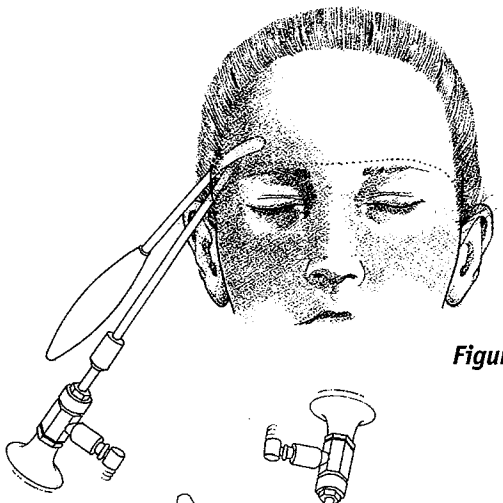


Figure 5

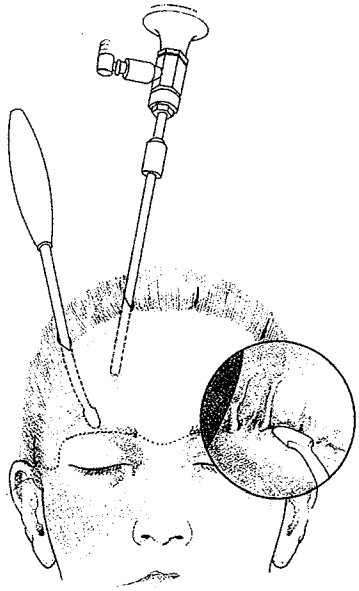


Figure 6

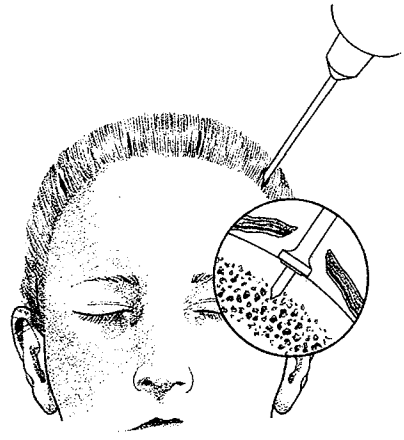


Figure 7

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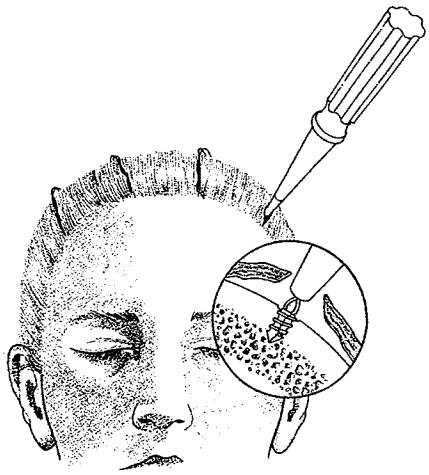

Figure 8

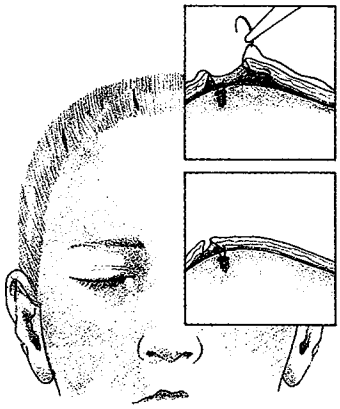

Figure 9

inserted through each of the predrilled holes on the frontal bone by turning the inserter in a clockwise fashion perpendicular to the outer cortex. ***(Figure 8)*** Release of the suture anchor will be automatic. The inserter is removed, taking care not to dislodge the suture from the anchor. The free end of the suture is threaded through the eyelet of a French-eye needle. Starting on the anterior edge of the scalp incision, the suture is passed through the subdermis, galea aponeurotica, and periosteum, taking a generous bite of the soft tissue. The sutures are tied under direct vision while carefully examining the brow for proper positioning. ***(Figure 9)*** The sutures controlling the lateral brow position should be tied first since these hold the greatest amount of tension. An assistant should support the forehead flap to reduce tension and avoid breaking the suture. After tying all the sutures, a final check for symmetry is made. If needed, an ellipse of full thickness skin is excised from the temporal incision to control for skin laxity and lateral periorbital wrinkling (crow's feet).

To avoid alopecia, all wounds are simply closed with a stapling device. The wounds are dressed with antibiotic ointment and a snug head dressing is applied. The patient is awakened from anesthesia and delivered to the recovery area. Prophylactic antibiotics and steroids are used according to each surgeon's discretion. The head dressing is removed after 24 hours and no further dressings are necessary. The staples are removed on the 7th to 10th postoperative day.

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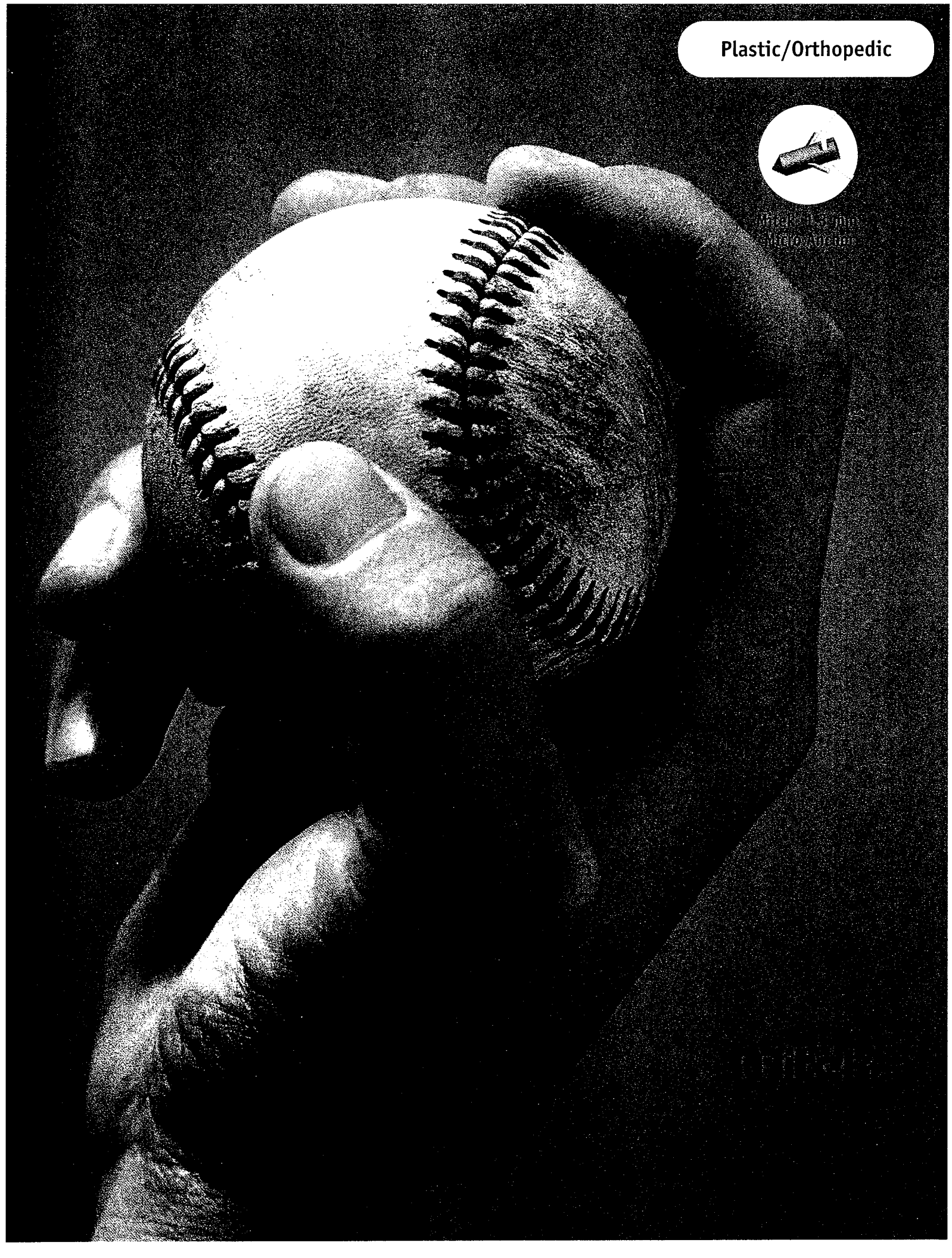


The Mitek® 1.3 mm M

Superior Fixation for Precise Techniques

Hand reconstructive operations are delicate procedures. Success depends on strong tissue reattachments. The Mitek 1.3 mm Micro Anchor responds to all conditions.

The 1.3 mm Micro Anchor locks nonabsorbable, 4/0 white ETHIBOND* Excel surgical suture into predrilled bone sites, firmly anchoring soft tissues to bone. It fastens tightly into subcortical cancellous bone. The anchor's tiny size and simplified instrumentation provide operative flexibility and placement into previously inaccessible sites.

These qualities make the Mitek 1.3 mm Micro Anchor effective in many intricate reconstructive surgeries, such as profundus tendon reattachment and collateral ligament reconstruction.

Small

Micro Anchor's miniature size facilitates placement of multiple anchors for greater intraoperative and postsurgical strength.

Versatile

Micro Anchor's design enables placement in previously inaccessible sites for greater surgical versatility.

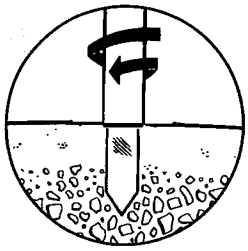
Secure

Micro Anchor's fixation is secure, with twice the USP strength requirement for 4/0 suture.

The Procedure

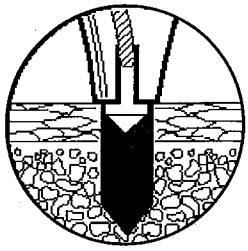
Inserting the Mitek 1.3 mm Micro Anchor

Specialized instruments facilitate placement of the Mitek 1.3 mm Micro Anchor: the drill and the inserter. With these, positioning is simple and fixation is secure.



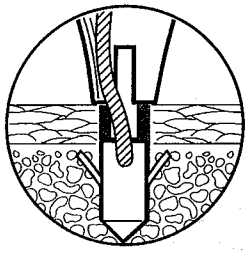
Drill the Hole

- Using the drill, prepare the anchor's insertion site.



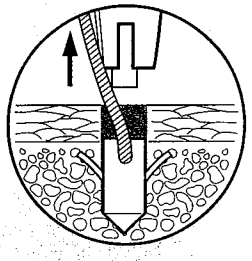
Place the Anchor

- Place the inserter sleeve on the perimeter of the predrilled hole.
- Establish the correct axial alignment of the inserter to the hole.



Insert the Anchor

- Holding the plastic handle of the inserter, push the thumb slide on the handle toward the drill hole until thumb slide stops, causing the anchor to implant.
- Withdraw the inserter to deploy the suture.



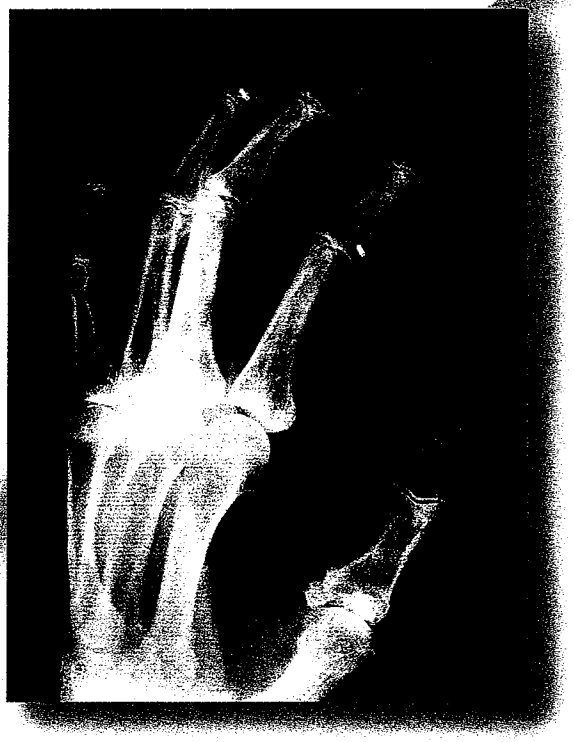
Set the Anchor

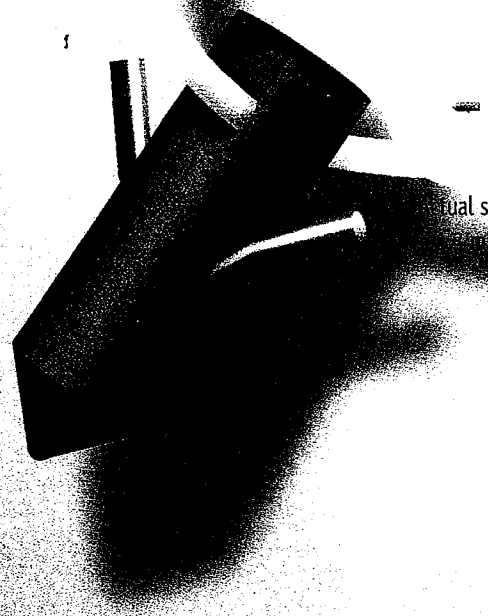
- Apply nominal tension (approximately 1 lb) on the lengths of suture to set the anchor in the hole.
- Use free needle to place suture in soft tissue.

icro Anchor

Mitek
Revolutionary Designs.
Multispecialty Applications.
The Gold Standard.

Worldwide, Mitek Anchors set the gold standard for soft tissue reattachment. Mitek's unique proprietary suture anchor product lines enhance a wide range of surgical techniques, speeding operational success. That's why Mitek is the first name in suture anchors.



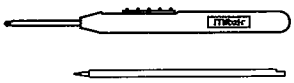


tual size:

Mitek®

The First Name In Suture Anchors.™

Ordering Information

Cat. No.	Description	Quantity
212991	Mitek 1.3 mm Micro Anchor and Drill†  	1/box
212995	Mitek 1.3 mm Micro Anchor and Drill†	5/box

†Only available preattached to 4/0 white ETHIBOND* Excel suture and preassembled with a single-use inserter.

Physician's authorization *Date*

For more information on the Mitek® 1.3 mm Micro Anchor, call your Mitek representative or **1-800-382-4682.**

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P/N 900199 Rev. A 2/97

Plastic/Reconstructive

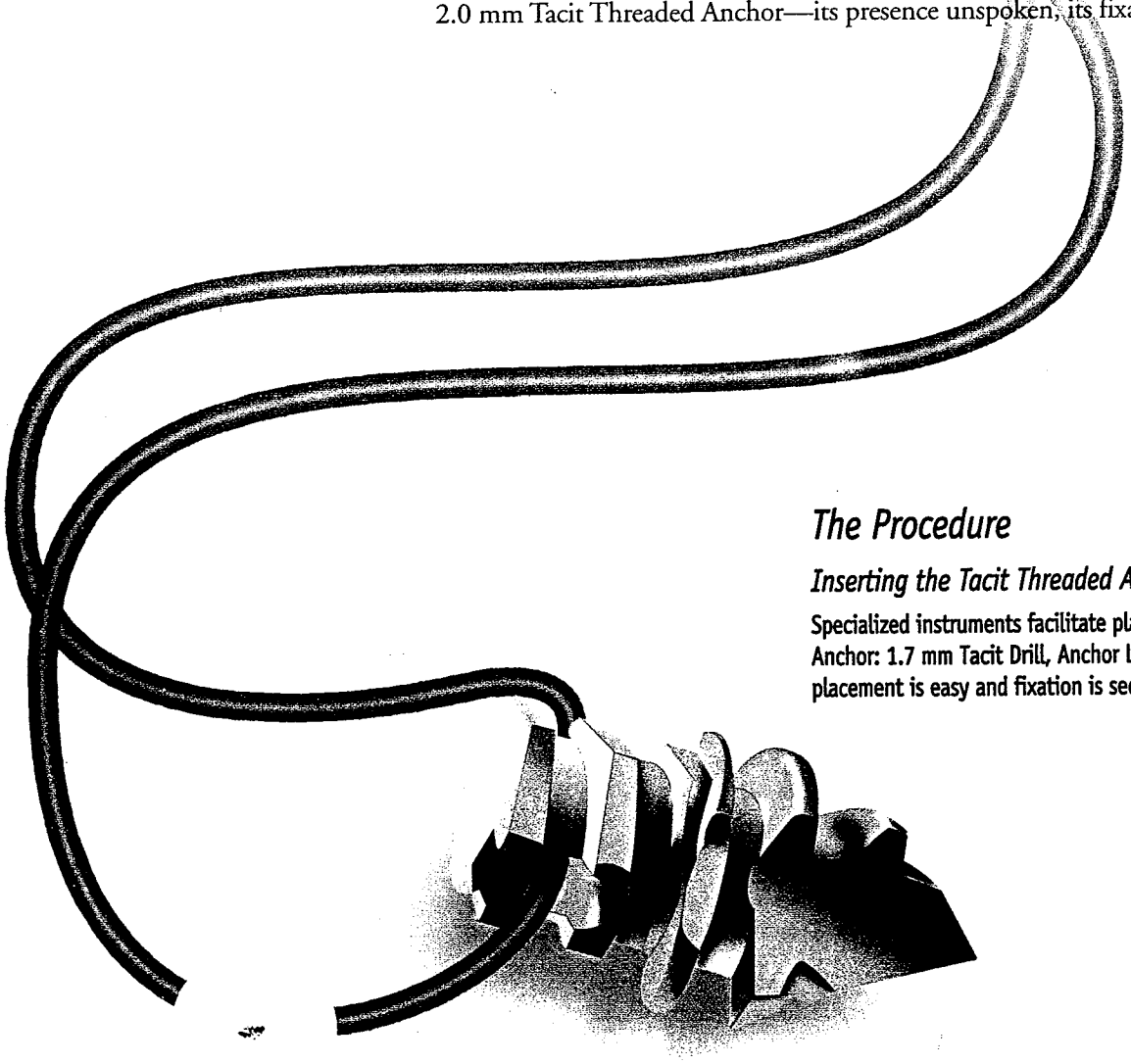
Mitek® 2.0 mm Tacif
Threaded Anchor

Mitek®

The Mitek® 2.0 mm T

Smaller Size. Superior Strength. Increased Safety.

Plastic and reconstructive surgery is an exact art, demanding absolute accuracy for optimal alignment. Surgeons must be able to precisely reattach tissue to bone to realize optimal results, not be hampered by operative constraints. Patient safety is paramount, just as lasting results are critical. Yet, achieving all this is not always simple. That is why Mitek designed the 2.0 mm Tacit Threaded Anchor—its presence unspoken, its fixation secure.



Actual size:
2.0 mm

The Procedure

Inserting the Tacit Threaded Anchor

Specialized instruments facilitate placement of the Tacit Threaded Anchor: 1.7 mm Tacit Drill, Anchor Loop and Tacit Inserter. With these, placement is easy and fixation is secure.

cit™ Threaded Anchor

Tacit, a titanium alloy implant, locks suture in predrilled bone sites. Its miniaturized dimensions allow precise anatomical placement, simplifying intricate operations while facilitating a wide range of procedures from endoscopic brow lifts to scapholunate ligament reconstruction. Throughout the plastic and reconstructive fields, Tacit ensures optimal results.

Small

Tacit's miniaturized size allows intraoperative flexibility, permitting the surgeon to select the location for optimal fixation.

Strong

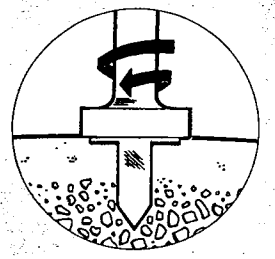
Tacit's fixation strength in cortical bone is more than twice the break strength of #2/0 suture.

Safe

With an anchor depth of only 4.0 mm, Tacit offers solid security, as proven in biomedical and clinical evaluations.

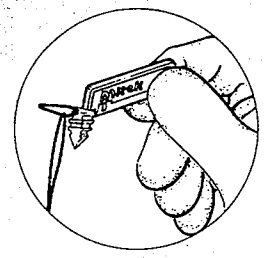
Mitek Revolutionary Designs. Multispecialty Applications. The Gold Standard.

Worldwide, Mitek Anchors set the gold standard for soft tissue reattachment. Mitek's unique proprietary suture anchor product lines enhance a wide range of surgical techniques, speeding operational success. That's why Mitek is the first name in suture anchors.



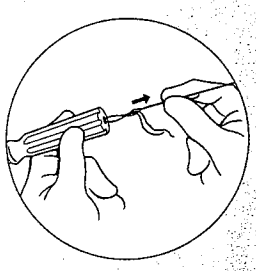
Drill the Hole

Using the drill, prepare the anchor's insertion site.



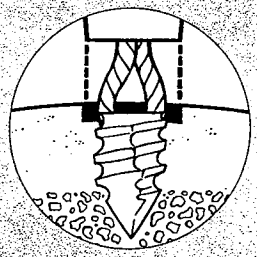
Thread the Suture

- To attach a single strand of braided suture, 2/0 or smaller, to Tacit:
  - — Pass the suture through threader tab wire.
  - — Pull the anchor off the threader into the middle of the suture.
  - — Discard the threader.
- To attach a monofilament suture, 3/0 or smaller, to Tacit:
  - — Place the suture directly through the anchor eyelet.



Attach Anchor to Loop

- Place Tacit with suture into the loop, leaving 5-6 inches of suture lead.
- Place the nonloop end into the hole in the metal tip of the inserter.
- Pull the loop through the inserter, grasping the nonloop end.
- Pull the suture taut while adjusting the anchor into the hex; this secures the anchor.



Insert the Anchor

- Using the inserter, place the anchor tip into the drill hole and establish axial alignment.
- Twist inserter clockwise until anchor disengages (approximately four revolutions).
- Remove inserter.

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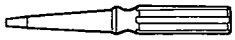
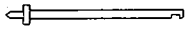
Ordering Information

Cat. No.	Description	Quantity
222120	Mitek 2.0 mm Tacit Threaded Anchor 	1/box
222520	Mitek 2.0 mm Tacit Threaded Anchor	5/box
219120	Tacit Inserter 	1/box
211002	1.7 mm Tacit Drill 	1/box
214567	Anchor Loop	1/box

For more information on the Mitek® 2.0 mm Tacit™ Threaded Anchor call your Mitek representative or **1-800-382-4682.**

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